NIH PRAGMATIC TRIALS COLLABORATORY

Rethinking Clinical Trials®

NIH Pragmatic Trials Collaboratory Onboarding Meeting

November 1, 2023

Virtual

SUPPLEMENTAL MEETING MATERIALS

Table of Contents

Agenda 4

NIH Collaboratory Handouts

- Organizational Chart 7
- Communication Channels 8
- Demonstration Project Roadmap 9
- Program Overview Handout 10
- Metrics Handout 12
- Publications Process Handout 14
- Onboarding—Data and Resource Sharing Informational Document 16
- Onboarding—Data and Resource Sharing Questionnaire 26
- Onboarding—Data and Resource Sharing Checklist 31
- Closeout—Data and Resource Sharing Checklist 33

Abstracts

- **AIM-CP:** Adapting and Implementing a Nurse Care Management Model to Care for Rural Patients with Chronic Pain 36
- **ARBOR-Telehealth:** Advancing Rural Back Pain Outcomes through Rehabilitation Telehealth 38
- **I CAN DO Surgical ACP:** Improving Completion, Accuracy, and Dissemination of Surgical Advanced Care Planning Trial 40
- **iPATH:** Implementing Scalable, PAtient-centered Team-based Care for Adults with Type 2 Diabetes and Health Disparities 42
- **MOMs:** Maternal OutcoMes Program: Testing Integrated Maternal Care Model Approaches to Reduce Disparities in Severe Maternal Morbidity 43
- **RAMP:** Reaching Rural Veterans: Applying Mind-Body Skills for Pain Using a Whole Health Telehealth Intervention 44

Barriers Scorecards

- AIM-CP 47
- ARBOR-Telehealth 48
- I CAN DO Surgical ACP 49
- iPATH 50
- MOMs 51
- RAMP 52

Data and Resource Sharing Plans

- AIM-CP 54
- ARBOR-Telehealth 56
- I CAN DO Surgical ACP 61

MOMs 63
RAMP 69
NIH Collaboratory Policies and Guidelines
Data Sharing Policy 73
Data Sharing Considerations....74
Data Quality Policy (Assessing Fitness-for-Use of Clinical Data for PCTs) 78
Publications, Presentations, and Products Policy....80
Study Snapshots for Seasoned Projects
ABATE: Active Bathing to Eliminate Infection....95
ACP PEACE: Improving Advance Care Planning: Promoting Effective and Aligned Communication in the Elderly....97
BackInAction: Pragmatic Trial of Acupuncture for Chronic Low Back Pain in Older Adults 99
FM-TIPS: Fibromyalgia TENS in Physical Therapy Study 101
INSPIRE: INtelligent Stewardship Prompts to Improve Real-time Empiric Antibiotic Selection for Patients....103
NOHARM: Nonpharmacologic Options in Postoperative Hospital-based and Rehabilitation Pain Management....104
Nudge: Personalized Patient Data and Behavioral Nudges to Improve Adherence to Chronic Cardiovascular Medications 106
PPACT: Collaborative Care for Chronic Pain in Primary Care....108
PROVEN: Pragmatic Trial of Video Education in Nursing Homes 110

NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

Virtual Onboarding Meeting
November 1, 2023
11:00 a.m. – 3:00 p.m.

Agenda

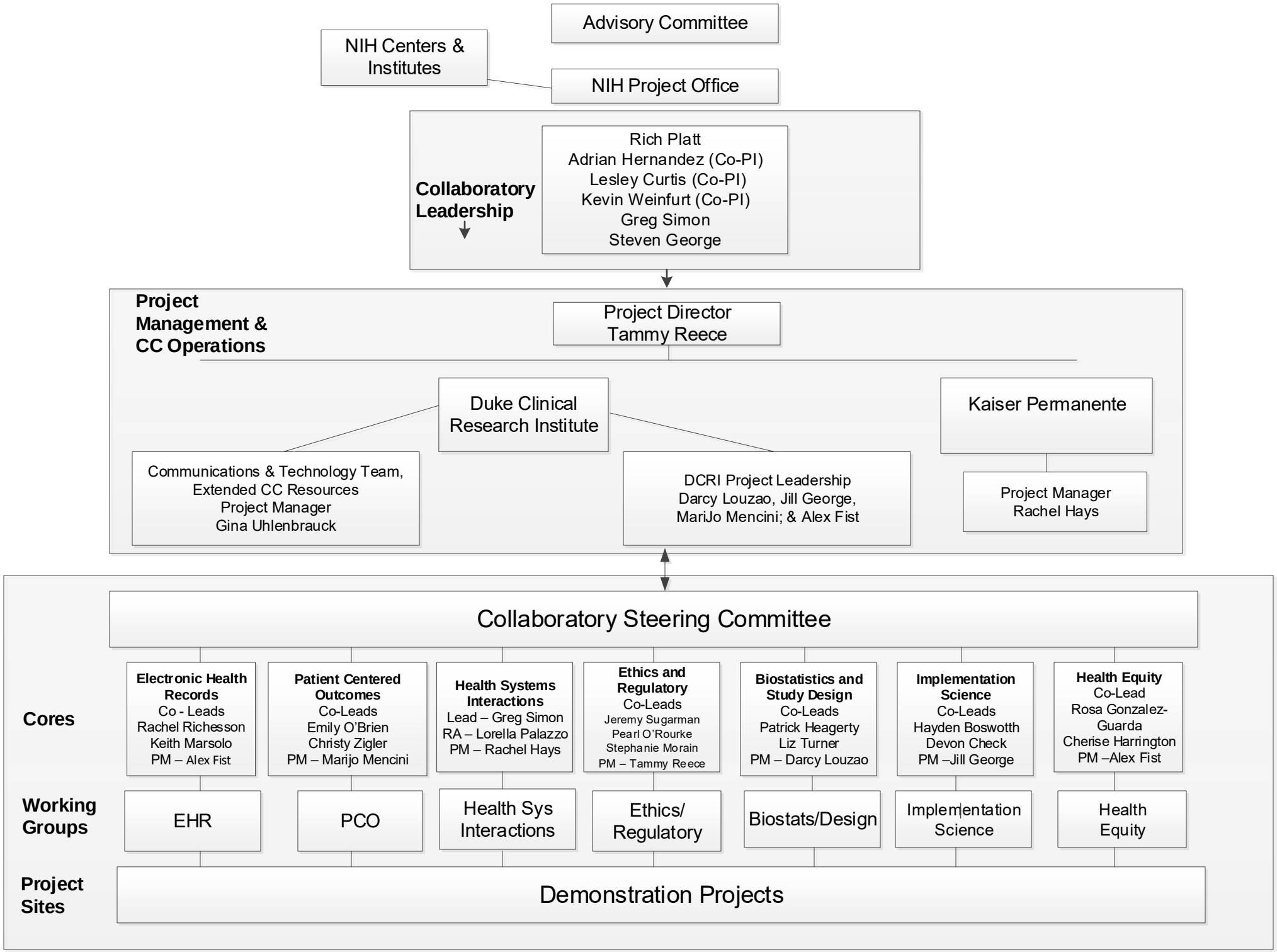
Meeting Purpose

Welcome and hear from the new Demonstration Projects; provide introductions and an overview of the NIH Pragmatic Trials Collaboratory program; and share lessons learned from the seasoned Demonstration Projects.

DURATION	TOPIC	WHO	GOAL
11:00 – 11:05 a.m.	**Welcome** **Opening Remarks**	Wendy Weber Lesley Curtis	*Review meeting goals and expectations* *Provide introductions*
11:05 – 11:20 a.m.	**Overview of the NIH Pragmatic Trials Collaboratory and a Cooperative Agreement**	Beda Jean-Francois	*Learn about the NIH Pragmatic Trials Collaboratory* *Look at innovative thinking about embedded pragmatic clinical trials* *Discuss what it means to be part of a cooperative agreement. Reinforce the idea of identifying and openly discussing issues and challenges with this community.*
11:20 – 11:35 p.m.	**NIH Collaboratory Coordinating Center: Overview and Goals**	Lesley Curtis	*Give an overview of the Coordinating Center* *Describe how Demonstration Projects work with the Coordinating Center* *Understand interactions with the Core Working Groups* *Discuss lessons learned and goals*
11:35 – 11:50 a.m.	**Program Policies and Guidance Documents** • Data Sharing Policy and Considerations • Data Quality Guidance • Publications, Presentations, and Products Policy	Rich Platt Gina Uhlenbrauck	*Provide a high-level review of the NIH Collaboratory policies and guidance documents* *Describe the Data and Resource Sharing process* *Learn the importance of the publications policy and tips for navigating the process*
11:50 – 12:05 p.m.	**Break**		

DURATION	TOPIC	WHO	GOAL
12:05 – 2:05 p.m.	**Discussion of New Demonstration Projects** **20 min each** o *15-min overview/status* o *5-min discussion with projects, program leadership, and Core leaders* • Implementing Scalable, PAtient-centered Team-based Care for Adults with Type 2 Diabetes and Health Disparities (iPATH) • Adapting and Implementing a Nurse Care Management Model to Care for Rural Patients with Chronic Pain (AIM-CP) • I CAN DO Surgical ACP (Improving Completion, Accuracy, and Dissemination of Surgical Advanced Care Planning) Trial • Maternal OutcoMes (MOMs) Program: Testing Integrated Maternal Care Model Approaches to Reduce Disparities in Severe Maternal Morbidity • Reaching Rural Veterans: Applying Mind-Body Skills for Pain Using a Whole Health Telehealth Intervention (RAMP) • Advancing Rural Back Pain Outcomes through Rehabilitation Telehealth (ARBOR-Telehealth)	 Sara Singer Sebastian Tong Kushang Patel Elizabeth Wick Genevieve Melton-Meaux Rebecca Sudore Stephanie Fitzpatrick Diana Burgess Roni Evans Katherine Hadlandsmyth Richard Skolasky Kevin McLaughlin	*Project abstracts and data sharing plans are in the meeting e-binder* *Provide an overview of each new project to include its status, top issues being faced, and potential barriers for successful implementation* *Q&A with program leadership*
2:05 – 2:55 p.m.	**Lessons Learned From Seasoned Demonstration Projects**	**<u>Moderator</u>** Adrian Hernandez **<u>Panel</u>** Lynn Debar Angelo Volandes Susan Huang Mike Ho Kathleen Sluka Andrea Cheville Leslie Crofford	*Project study snapshots are in the meeting e-binder* *Share lessons learned during the UG3 and UH3 phases* *Top lesson learned/experience* *Describe tips for managing Year 1* • *Core calls* • *Balance delegating activities and staying in the loop* • *Deliverables and milestones* • *Administrative requirements* ***Includes time for Q&A***
2:55 – 3:00 p.m.	**Closing Remarks**	Wendy Weber Adrian Hernandez	*Summarize the day*

NIH COLLABORATORY HANDOUTS


Advisory Committee
NIH Centers & Institutes
NIH Project Office
Collaboratory Leadership
Rich Platt
Adrian Hernandez (Co-PI)
Lesley Curtis (Co-PI)
Kevin Weinfurt (Co-PI)
Greg Simon
Steven George
Project Management & CC Operations
Project Director
Tammy Reece
Duke Clinical Research Institute
Kaiser Permanente
Communications & Technology Team,
Extended CC Resources
Project Manager
Gina Uhlenbrauck
DCRI Project Leadership
Darcy Louzao, Jill George,
MariJo Mencini; & Alex Fist
Project Manager
Rachel Hays
Collaboratory Steering Committee
Cores
Electronic Health Records
Co - Leads
Rachel Richesson
Keith Marsolo
PM – Alex Fist
Patient Centered Outcomes
Co-Leads
Emily O'Brien
Christy Zigler
PM – Marijo Mencini
Health Systems Interactions
Lead – Greg Simon
RA – Lorella Palazzo
PM – Rachel Hays
Ethics and Regulatory
Co-Leads
Jeremy Sugarman
Pearl O'Rourke
Stephanie Morain
PM – Tammy Reece
Biostatistics and Study Design
Co-Leads
Patrick Heagerty
Liz Turner
PM – Darcy Louzao
Implementation Science
Co-Leads
Hayden Boswotth
Devon Check
PM –Jill George
Health Equity
Co-Lead
Rosa Gonzalez-Guarda
Cherise Harrington
PM –Alex Fist
Working Groups
EHR
PCO
Health Sys Interactions
Ethics/ Regulatory
Biostats/Design
Implementation Science
Health Equity
Project Sites
Demonstration Projects

NIH PRAGMATIC TRIALS COLLABORATORY COMMUNICATIONS CHANNELS

NIH INSTITUTES & CENTERS

HEAL INITIATIVE

Title: ACP PEACE

PIs:
James A. Tulsky
Angelo Volandes

Institution:
Dana-Farber Cancer Institute

Title: AIM-CP

PIs:
Sebastian Tong
Kushang Patel

Institution:
University of Washington

Title: ARBOR-Telehealth

PIs:
Richard Skolasky
Kevin McLaughlin

Institution:
Johns Hopkins University

Title: BackInAction

PIs:
Lynn DeBar
Andrea Cook

Institution:
Kaiser Foundation Research Institute

Title: BeatPain Utah

PI:
Julie Fritz

Institution:
University of Utah

Title: BEST-ICU

PIs:
Michele Balas
Eduard Vasilevskis

Institution:
University of Nebraska Medical Center

Title: Chat 4 Heart Health

PIs:
Michael Ho
Sheana Bull

Institution:
University of Colorado

Title: FM-TIPS

PIs:
Kathleen Sluka
Leslie Crofford

Institution:
University of Iowa

Title: GGC4H

PIs:
Margaret Kuklinski
Stacy Sterling

Institution:
University of Washington

Title: GRACE

PIs:
Ardith Doorenbos
Judith Schlaeger
Robert Molokie
Miriam Ezenwa
Nirmish Shah

Institution:
University of Illinois at Chicago

Title: HiLo

PI:
Myles Wolf

Institution:
Duke University

Title: ICD-Pieces™

PI:
Miguel Vazquez

Institution:
University of Texas Southwestern Medical Center

Title: I CAN DO Surgical ACP

PIs:
Elizabeth Wick
Genevieve Melton-Meaux
Rebecca Sudore

Institution:
University of California, San Francisco

Title: IMPACt-LBP

PIs:
Christine Goertz
Adam Goode
Jon Lurie
Hrishikesh Chakraborty

Institution:
Duke University

Title: INSPIRE

PIs:
Susan Huang
Richard Platt
Shruti Gohil

Institution:
Harvard Pilgrim Health Care

Title: iPATH

PI:
Sara Singer

Institution:
Stanford University

Title: MOMs

PI:
Stephanie Fitzpatrick

Institution:
Feinstein Institute for Medical Research

Title: NOHARM

PIs:
Andrea Cheville
Jon Tilburt

Institution:
Mayo Clinic

Title: Nudge

PIs:
Michael Ho
Sheana Bull

Institution:
University of Colorado

Title: OPTIMUM

PI:
Natalia Morone

Institution:
Boston Medical Center

Title: PRIM-ER

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Keith Goldfeld

Institution:
NYU School of Medicine

Title: RAMP

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Roni Evans
Katherine Hadlandsmyth

Institution:
Center for Veterans Research and Education

Title: TAICHIKNEE

PIs:
Chenchen Wang
Helen Lavretsky
Eric Roseen
Robert Saper

Institution:
Tufts Medicine Tufts Medical Center

DEMONSTRATION PROJECTS

Demonstration Project PI	Project Officer	Project Officer IC	Project Scientist	Project Scientist IC
Miguel Vazquez	Susan Mendley	NIDDK	Kevin Chan	NIDDK
Margaret Kuklinski	Beda Jean-Francois	NCCIH/NIDA	Elizabeth Ginexi	NCCIH
Corita Grudzen	Peter Murray	NCCIH	Marcel Salive	NIA
Michael Ho	Larry Fine	NHLBI	Nicole Redmond	NHLBI
James Tulsky	Marcel Salive	NIA	Karen Kehl	NINR
Myles Wolf	Susan Mendley	NIDDK	Kevin Chan	NIDDK
Lynn DeBar	Lanay Mudd	NCCIH	Basil Eldadah	NIA
Andrea Cheville	Marcel Salive	NIA	Theresa Cruz	NICHD/NCMRR
Kathleen Sluka	Charles Washabaugh	NIAMS	Joe Bonner	NINR
Natalia Morone	Wendy Weber	NCCIH	Luke Stoeckel	NIA
Ardith Doorenbos	Beda Jean-Francois	NCCIH	Beda Jean-Francois	NCCIH
Julie Fritz	Karen Kehl	NINR	Joe Bonner	NICHD/NCMRR
Christine Goertz	Peter Murray	NCCIH	TBD	TBD
Shruti Gohil	Clayton Huntley	NIAID	Clayton Huntley	NIAID
Michele Balas	Mihaela Stefan	NHLBI	Karen Kehl	NINR
Chenchen Wang	Sekai Chideya	NCCIH	Lanay Mudd & Qilu Yu	NCCIH
Michael Ho	Larry Fine	NHLBI	Nicole Redmond	NHLBI
Elizabeth Wick	Barbara Radziszewska	NIA	Marcel Salive	NIA
Stephanie Fitzpatrick	Shalanda Bynum	NINR	NA	NA
Sara Singer	Lynne Slaughter Padgett	NIMHD	NA	NA
Sebastian Tong	Karen Kehl	NINR	Alexis Bakos	NIA
Diana Burgess	Karen Kehl	NINR	Lanay Mudd	NCCIH
Richard Skolasky	Charles Washabaugh	NIAMS	TBD	TBD
Coordinating Center PIs	**Project Officer**	**Project Officer IC**	**Project Scientist**	**Project Scientist IC**
Adrian Hernandez Lesley Curtis Kevin Weinfurt	Wendy Weber	NCCIH	Robin Boineau	NCCIH

COLLABORATORY COORDINATING CENTER

STEERING COMMITTEE

Lesley Curtis (Chair)
Michele Balas
Alexis Bakos
Robin Boineau
Joe Bonner
Hayden Bosworth
Sheana Bull
Diana Burgess
Shalanda Bynum
Hrishikesh Chakraborty
Kevin Chan
Devon Check
Andrea Cheville
Sekai Chideya
Andrea Cook
Leslie Crofford
Theresa Cruz
Lynn DeBar
Ardith Doorenbos
Debra Egan
Basil Eldadah
Roni Evans
Miriam Ezenwa
Lawrence Fine
Stephanie Fitzpatrick
Julie Fritz
Elizabeth Ginexi
Christine Goertz
Shruti Gohil
Keith Goldfeld
Rosa Gonzalez-Guarda
Adam Goode
Corita Grudzen
Katherine Hadlandsmyth
Cherise Harrington
Patrick Heagerty
Adrian Hernandez
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Susan Mendley
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Robert Molokie
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Lanay Mudd
Peter Murray
Emily O'Brien
Pearl O'Rourke
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Kushang Patel
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Barbara Radziszewska
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Sara Singer
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Kathleen Sluka
Mihaela Stefan
Stacy Sterling
Luke Stoeckel
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Sebastian Tong
James Tulsky
Liz Turner
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Miguel Vazquez
Angelo Volandes
Chenchen Wang
Charles Washabaugh
Wendy Weber
Kevin Weinfurt
Elizabeth Wick
Myles Wolf
Qilu Yu
Christy Zigler

NIH PROJECT OFFICE

NIH INSTITUTES AND CENTERS

NHLBI NIAID NIDDK NIAMS NCCIH NIDA NIA NINR NICHD NCMRR NIMHD

KNOWLEDGE REPOSITORY

LEARNING HEALTH SYSTEM

COLLABORATORY CORE WORKING GROUPS

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Joe Ali
Andy Avins
Sheana Bull
Leslie Crofford
Laura Dember
Dixie Ecklund
Janel Fedler
Carole Frederico
Andrew Garland
Susan Gaylord
Bryan Gibson
Corita Grudzen
Breanna Hetland
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Mitch Knisely
Margaret Kuklinski
Laurie Kunches
Helen Lavretsky
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Natalia Morone
Tina Neill-Hudson
Vasiliki Nataly Rahimzadeh
Tammy Reece
Marguerite Robinson
Judy Schlaeger
Kayte Spector-Bagdady
Venky Sundaram
Paula Tebeau
Jon Tilburt
David Vulcano
Chenchen Wang
Kevin Weinfurt
Dave Wendler
Ben Wilfond

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Patrick Heagerty*
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Taliser Avery
Emine Bayman
Evan Carey
Hrishikesh Chakraborty
Yuchiao Chang
Andrea Cook
Ardith Doorenbos
Keith Goldfeld
Tom Greene
Gary Grunwald
Liz Habermann
Jeph Herrin
Ken Kleinman
Margaret Kuklinski
Karen Lasser
Fan Li
Darcy Louzao
Jon Moyer
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Charles Quesenberry
Jincheng Shen
Prabha Siddarth
Alana Steffen
Yu Ru Su
Ludovic Trinquart
Neha Varma
Angelo Volandes
Jin Wang
Rui Wang
Xueqi Wang
Janice Weinberg
Christopher Wickman
Myles Wolf
Qilu Yu

HEALTH CARE SYSTEMS INTERACTIONS

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James Blum
Jordan Braciszewski
Sheana Bull
David Chambers
Lynn DeBar
Laura Dember
Rowena Dolor
Matt Exline
Julie Fritz
Corita Grudzen
Rachel Hays
Jacob Hill
Michael Ho
Barcey Levy
Jon Lurie
Timothy McAlindon
Sarah Minteer
Natalia Morone
Lorella Palazzo
Crystal Patil
Pamela Peterson
Russell Poland
Kathleen Sluka
Victor Solis
Stacy Sterling
Jon Tilburt
Kenneth Sands
Katie Stone
Carol Vance
Angelo Volandes
Weijun Zhang

ELECTRONIC HEALTH RECORDS

Rachel Richesson*
Keith Marsolo*
Liz Amos
Taliser Avery
Arne Beck
Srinivasan Beddhu
Andy Boyd
Jordan Braciszewski
James Campbell
Andrea Cheville
Dana Dailey
Kim Faurot
Alex Fist
Guilherme del Fol
Carol Geary
Christine Goertz
Corita Grudzen
Ed Hammond
Michael Ho
Trevis Huff
Andrea Kline-Simon
Josh Lakin
Andy MacKelfresh
Devin Mann
Clem McDonald
Laura McLean
Kathleen McTigue
Meg Plomondon
Alice Pressman
Kiran Salman
Robert Saper
Stacy Sterling
Ludovic Trinquart
Angelo Volandes

PATIENT-CENTERED OUTCOMES

Christy Zigler*
Emily O'Brien*
Michele Balas
Emine Bayman
Arne Beck
M. Fernanda Bellolio
Andy Boyd
Andrea Cheville
Leslie Crofford
Susan Czajkowski
Morgan Fuoco
Adam Goode
Carol Greco
Tamara Isakova
Chris Knoepke
Margaret Kuklinski
Helen Lavretsky
Amy Loree
MariJo Mencini
Tuhina Neogi
Monica Perez Jolles Pamela Peterson
Alana Steffen
Stacy Sterling
Anne Thackeray
Jon Tilburt
James Tulsky
Eduard Vasilevskis
Chenchen Wang
Kevin Weinfurt

HEALTH EQUITY

Rosa Gonzalez-Guarda*
Cherise Harrington*
Maureen Akubu-Odero
Jessica Lee Barnhill
Sheana Bull
Gaby Castro
Andrea Cheville
Allison Cuthel
Dana Dailey
Juanita Darby
Stacie Daughter
Graham Dore
Kim Faurot
Alex Fist
Julie Fritz
Morgan Fuoco
Christine Goertz
Ronnie Horner
Beda Jean-Francois
Jungyoon Kim
Mitchell Knisely
Lance Laird
Katharine Lawrence
Nadine Matthie
Alice Pressman
Isabel Roth
Robert Saper
Nina Siman
Rebecca Sudore
Venky Sundaram

IMPLEMENTATION SCIENCE

Devon Check *
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Kristin R. Archer
Lindsay Ballengee
Gaby Castro
Allison Cuthel
Ardith Doorenbos
Jill George
Steven George
Tony Gerlach
Shruti Gohil
Carol Greco
Anna Krupp
Sarah Minteer
Brian Mittman
Wynne Norton
Crystal Patil
Eric Roseen
Isabel Roth
Stacie Salsbury
Edward Septimus
Stacy Sterling
Anne Thackeray
Cindy Tofthagen
Katy Trinkley
Angelo Volandes

Chair / Co-Chairs

Current as of: October 2023

NIH Collaboratory Demonstration Project Roadmap
FY23, Q4

Milestones and major activities occurring within the lifecycle of a Collaboratory Demonstration Project

PILOT/START-UP

- UG3 Award Date
- R01 Award Date *

AIM-CP, ARBOR-Telehealth, BEST-ICU, Chat 4 Heart Health, I CAN DO Surgical ACP, iPATH*, MOMs*, RAMP, TAICHIKNEE

IMPLEMENTATION

- UH3 Award
- Trial Registration
- Protocol Approved for Implementation
- Initial IRB Approval (UH3 Phase Implementation)
- Initial IRB Approval (R01)
- Statistical Analyses Plan Finalized

SITE ACTIVATION

- First Site Activated

ENROLLMENT

- First Patient Enrolled

BeatPain Utah, FM TIPS, GRACE, HiLo, IMPACt-LBP, INSPIRE, NOHARM

FOLLOW-UP

- Last Patient Enrolled
- Last Day for Intervention
- End of Outcome Observation Period

ACP PEACE, BackInAction, GGC4H, OPTIMUM

DATA AVAILABILITY

- Key Data Available
- Secondary Endpoint Data Available
- All Data Available

PRIM-ER

DATA ANALYSIS

- Database Lock
- Final Statistical Analysis

Nudge

REPORTING: Internal Dissemination

- Topline Results Report
- Topline Results (or Full Results) to Health System Partners
- Topline Results to Leadership/SC and Other Stakeholders
- Topline Results to Investigators/Sites

REPORTING: Public Dissemination

- Topline Results to Public via Press Release (if done)
- Full Results to Public
- First Presentation Results
- Main Manuscript Submitted
- Main Manuscript Accepted
- ClinicalTrials.gov Reporting

ABATE, EMBED, ICD-Pieces, LIRE, PPACT, PROVEN, SPOT, STOP CRC, TiME, TSOS

NIH PRAGMATIC TRIALS COLLABORATORY

Rethinking Clinical Trials®

NIH Pragmatic Trials Collaboratory

GOAL

Strengthen the national capacity to implement cost-effective, large-scale research studies that engage healthcare delivery organizations as research partners

WHAT ARE EMBEDDED PRAGMATIC CLINICAL TRIALS (EPCTS)?

Trials conducted within healthcare systems that use streamlined procedures and existing infrastructure to answer important medical questions. These trials have the potential to inform policy and practice with high-quality evidence at a reduced cost and increased efficiency compared with traditional clinical trials.

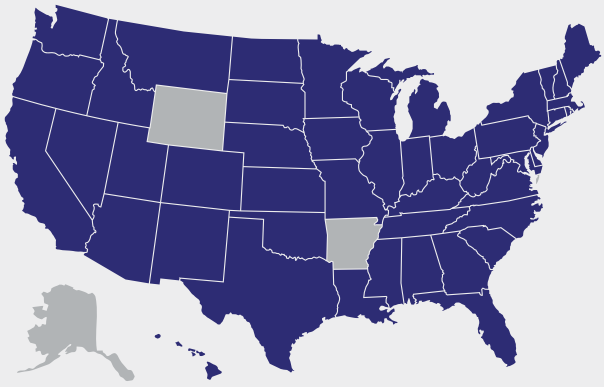
PROGRAM

DEMONSTRATION PROJECTS: ePCTs that address questions of major public health importance and provide proof of concept for innovative pragmatic research designs

CORES: Working groups that support the conduct of Demonstration Projects and generate guidance addressing implementation challenges

32 DEMONSTRATION PROJECTS

- Conducted in partnership with healthcare systems
- Studying diverse clinical areas spanning 13 NIH Institutes and Centers
- >1100 clinical sites across 94% of United States; >940,000 active subjects



RESOURCES

Living Textbook of Pragmatic Clinical Trials
Comprehensive resource on ePCTs

DESIGN describes how to plan an ePCT, including biostatistical and study design considerations, using electronic health record data, and building study teams and partnerships

DATA, TOOLS & CONDUCT describes tips for study startup, participant recruitment, data collection, and intervention delivery and monitoring

DISSEMINATION describes data sharing, dissemination, and implementation approaches

ETHICS AND REGULATORY describes issues related to privacy, informed consent, collateral findings, data and safety monitoring, and more

Plus:

- Grand Rounds webinars and podcasts
- Monthly NIH Collaboratory newsletter

Visit the Living Textbook: www.rethinkingclinicaltrials.org

This work was supported within the National Institutes of Health (NIH) Pragmatic Trials Collaboratory through cooperative agreement U24AT009676 from the National Center for Complementary and Integrative Health, the National Institute of Allergy and Infectious Diseases, the National Cancer Institute, the National Institute on Aging, the National Heart, Lung, and Blood Institute, the National Institute of Nursing Research, the National Institute of Minority Health and Health Disparities, the National Institute of Arthritis and Musculoskeletal and Skin Diseases, the NIH Office of Behavioral and Social Sciences Research, and the NIH Office of Disease Prevention. This work was also supported by the NIH through the NIH HEAL Initiative under award number U24AT010961.

HOW IS A CLINICAL TRIAL CONSIDERED PRAGMATIC?

An **EXPLANATORY** approach answers the question, "Can this intervention work under ideal conditions?"
A **PRAGMATIC** approach answers the question, "Does this intervention work under usual conditions?"

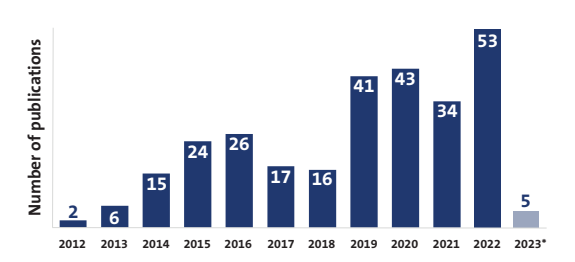
A trial's degree of pragmatism will vary along this spectrum:

Source: The PRECIS-2 tool: designing trials that are fit for purpose. BMJ 2015;350:h2147. PMID:25956159. doi:10.1136/bmj.h2147.

Visit the Living Textbook:
www.rethinkingclinicaltrials.org

NIH Pragmatic Trials Collaboratory Metrics

PEER-REVIEWED PUBLICATIONS



282 total

*As of April 2023

TOP LIVING TEXTBOOK CHAPTERS AND PAGES

April 1, 2022 – March 31, 2023

PAGE	VIEWS
Experimental Designs and Randomization Schemes: Cluster Randomized Trials	24,026
Home page	18,143
Choosing and Specifying Endpoints and Outcomes	6,090
Analysis Plan: Intraclass Correlation	4,013
Grand Rounds Hub	3,950
Experimental Designs and Randomization Schemes: Randomization Methods	3,077
Experimental Designs and Randomization Schemes: Choosing Between Cluster and Individual Randomization	2,385
About NIH Collaboratory	2,319
What Is a Pragmatic Clinical Trial?	2,089

MOST VIEWED NEWS POSTS

DATE	POST
May 24, 2022	FM-TIPS Seeks More Treatment Options for Patients With Fibromyalgia
August 10, 2022	NIH Pragmatic Trials Collaboratory Announces Grand Rounds Series on Ethical and Regulatory Challenges in Pragmatic Trials
May 23, 2022	NIH Pragmatic Trials Collaboratory Announces Virtual Workshop on Critical Questions for Pragmatic Clinical Trialists
March 16, 2022	Ivermectin Results From the TOGETHER Trial Will Be Shared in COVID-19 Grand Rounds

OUR FOLLOWING

2,164
@Collaboratory1 followers

1,484
Collaboratory email newsletter subscribers

16,381
all-time podcast plays

GRAND ROUNDS

476
total Grand Rounds presentations since inception

194
average attendees per week over the last year

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NIH PRAGMATIC TRIALS COLLABORATORY
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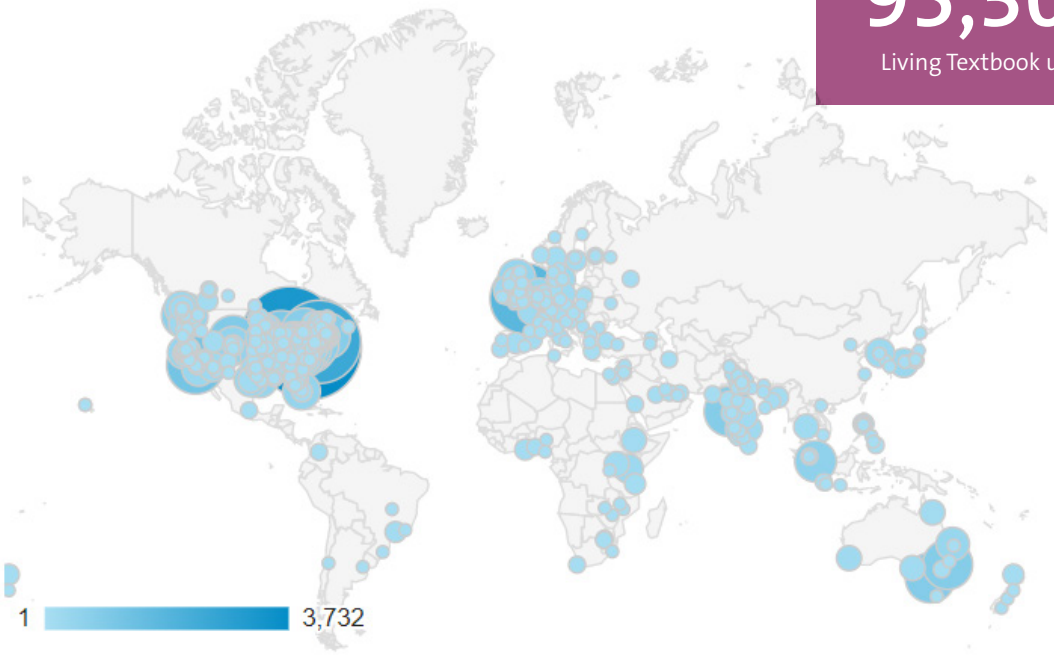
95,307
Living Textbook users



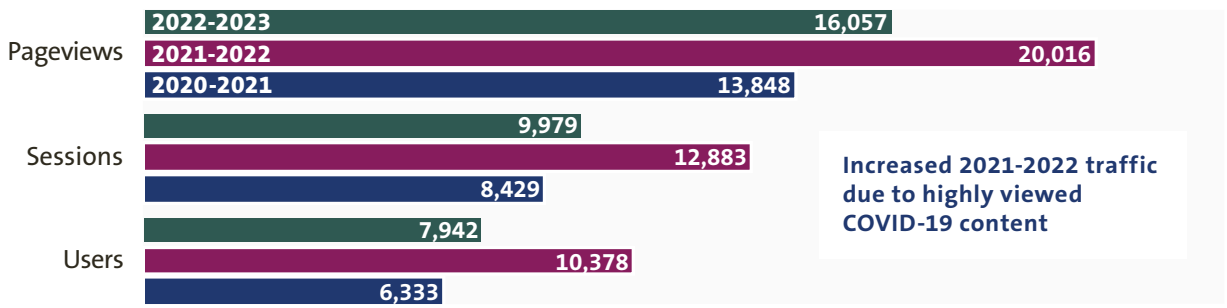
TOP 10 USER LOCATIONS

COUNTRY	USERS
United States	55,344
United Kingdom	6,085
Canada	3,756
India	3,454
Australia	2,959

COUNTRY	USERS
Germany	1,704
Japan	1,335
Netherlands	1,293
China	946
Philippines	931

The Pharmacological Evaluation Institute of Japan is translating the Living Textbook into Japanese!

AVERAGE MONTHLY LIVING TEXTBOOK TRAFFIC



Increased 2021-2022 traffic due to highly viewed COVID-19 content

This work was supported within the National Institutes of Health (NIH) Pragmatic Trials Collaboratory through cooperative agreement U24AT009676 from the National Center for Complementary and Integrative Health, the National Institute of Allergy and Infectious Diseases, the National Cancer Institute, the National Institute on Aging, the National Heart, Lung, and Blood Institute, the National Institute of Nursing Research, the National Institute of Minority Health and Health Disparities, the National Institute of Arthritis and Musculoskeletal and Skin Diseases, the NIH Office of Behavioral and Social Sciences Research, and the NIH Office of Disease Prevention. This work was also supported by the NIH through the NIH HEAL Initiative under award number U24AT010961.

NIH PRAGMATIC TRIALS COLLABORATORY

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(See reverse side for Coordinating Center and Core Publications)

The Demonstration Projects are supported by NIH Institutes, Centers, or Offices through either the NIH Pragmatic Trials Collaboratory or the NIH HEAL Initiative's PRISM program. The Coordinating Center provides logistical and technical support for all Demonstration Projects. For Demonstration Project publications, please complete these steps, as required by our policies and funding.

Before Publication

STEP 01

Choose option A, B, or C for the funding acknowledgment.

Option A: Your work is supported solely by an NIH Pragmatic Trials Collaboratory Demonstration Project.

Use the following language: "This work was supported within the National Institutes of Health (NIH) Pragmatic Trials Collaboratory by cooperative agreement [UG3/UH3 grant number] from the [Institute, Center, or Office providing funding or oversight]. This work also received logistical and technical support from the NIH Pragmatic Trials Collaboratory Coordinating Center through cooperative agreement U24AT009676 from the National Center for Complementary and Integrative Health (NCCIH), the National Institute of Allergy and Infectious Diseases (NIAID), the National Cancer Institute (NCI), the National Institute on Aging (NIA), the National Heart, Lung, and Blood Institute (NHLBI), the National Institute of Nursing Research (NINR), the National Institute of Minority Health and Health Disparities (NIMHD), the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), the NIH Office of Behavioral and Social Sciences Research (OBSSR), and the NIH Office of Disease Prevention (ODP). The content is solely the responsibility of the authors and does not necessarily represent the official views of [Institute, Center, or Office providing funding or oversight] or the NCCIH, NIAID, NCI, NIA, NHLBI, NINR, NIMHD, NIAMS, OBSSR, or ODP, or the NIH."

Option B: Your work is supported solely by a PRISM Demonstration Project.

Use the following language: "This work was supported within the National Institutes of Health (NIH) Pragmatic Trials Collaboratory through the NIH HEAL Initiative under award number [UG3/UH3 grant number] administered by the [Institute, Center, or Office providing oversight]. This work also received logistical and technical support from the PRISM Resource Coordinating Center under award number U24AT010961 from the NIH through the NIH HEAL Initiative. The content is solely the responsibility of the authors and does not necessarily represent the official views of the [Institute, Center, or Office providing oversight] or the NIH or its HEAL Initiative."

Option C: Your work has multiple sources of support.

For work with multiple sources of support—such as multiple Demonstration Projects, a collaboration between a Demonstration Project and the Coordinating Center or a Core Working Group, supplemental funding for specific activities, or support from outside the NIH Collaboratory—email us at nih-collaboratory@dm.duke.edu. We're here to help!

STEP 02

Does your work include a description of another Demonstration Project?

If yes, please allow the principal investigator of the other Demonstration Project to review your work. This courtesy review will be limited to the factual accuracy of your description of their work. Allow at least 2 weeks in advance of your initial journal submission.

Coordinating Center staff can facilitate this process and convey draft manuscripts to Demonstration Project investigators for their confidential review. Email us at nih-collaboratory@dm.duke.edu and include "Manuscript Review" in the subject heading.

STEP 03

Notify the Coordinating Center.

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Please allow 1 week for us to review your acknowledgment statement. Coordinating Center staff and the publications committee are also available to provide advice, suggestions, and help with dissemination, as needed.

After Publication

STEP 01

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Email us at nih-collaboratory@dm.duke.edu.

We track and report on publications as part of the NIH Collaboratory grants. We also want to share and promote your work!

STEP 02

Ensure your work meets applicable NIH public access requirements, such as inclusion in PubMed Central.

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NIH Collaboratory Coordinating Center and Core Publications

(See reverse side for Demonstration Project Publications)

For Coordinating Center and Core Working Group publications, please complete these steps, as required by our policies and funding.

Before Publication

STEP 01

Choose option A or B for your funding acknowledgment.

Option A: Some or all of your work is supported by the Coordinating Center or a Core Working Group.

Include the following language: "This work was supported within the National Institutes of Health (NIH) Pragmatic Trials Collaboratory through cooperative agreement U24AT009676 from the National Center for Complementary and Integrative Health (NCCIH), the National Institute of Allergy and Infectious Diseases (NIAID), the National Cancer Institute (NCI), the National Institute on Aging (NIA), the National Heart, Lung, and Blood Institute (NHLBI), the National Institute of Nursing Research (NINR), the National Institute of Minority Health and Health Disparities (NIMHD), the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), the NIH Office of Behavioral and Social Sciences Research (OBSSR), and the NIH Office of Disease Prevention (ODP). This work was also supported by the NIH through the NIH HEAL Initiative under award number U24AT010961. [If supplemental funding was provided for specific activities, then the Institute, Center, or Office providing the support should be acknowledged here.] The content is solely the responsibility of the authors and does not necessarily represent the official views of the NCCIH, NIAID, NCI, NIA, NHLBI, NINR, NIMHD, NIAMS, OBSSR, or ODP, or the NIH or its HEAL Initiative."

Option B: Your work has multiple sources of support in addition to the Coordinating Center or a Core Working Group.

For work with multiple sources of support in addition to the Coordinating Center or a Core Working Group—such as multiple Demonstration Projects, a collaboration between a Demonstration Project and the Coordinating Center or a Core Working Group, supplemental funding for specific activities, or support from outside the NIH Collaboratory—email us at nih-collaboratory@dm.duke.edu. We're here to help!

After Publication

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Onboarding Data and Resource Sharing Informational Document

Table of Contents

Purpose 2

Data Sharing Requirements for the NIH Pragmatic Trials Collaboratory, NIH, and Medical Journals 2

- NIH Pragmatic Trials Collaboratory Data Sharing Policy 2
- NIH Data Sharing Policy 3
- Medical Journal Data Sharing Requirements 3

Examples from NIH Pragmatic Trials Collaboratory Demonstration Projects 4

Data Sharing Mechanisms 7

Examples of Data Sharing Platforms 9

Examples of Data Sharing Statements 10

- Suicide Prevention Outreach Trial (SPOT) Data Sharing Statement 10
- NIH Pragmatic Trials Collaboratory Data Sharing Statement 10

Purpose

This document is meant to provide background and information to assist clinical investigators in developing data sharing plans and is to be used along with the accompanying Data Sharing Plan Development Worksheet. This document contains information on data sharing requirements for the NIH Pragmatic Trials Collaboratory, NIH, and medical journals; information on data sharing mechanisms and platforms; and examples from NIH Collaboratory Demonstration Projects.

If you have questions, feedback or suggestions regarding data sharing, please contact us at nih-collaboratory@dm.duke.edu.

Data Sharing Requirements for the NIH Pragmatic Trials Collaboratory, NIH, and Medical Journals

Please note that these policies are current as of the date of this document. Refer to the individual websites for the latest information and full requirements.

NIH Pragmatic Trials Collaboratory Data Sharing Policy

"1. Collaboratory investigators will each share, at a minimum, a final research data set upon which the accepted primary pragmatic trial publication is based.
2. The Collaboratory Steering Committee recognizes that sharing data derived from clinical care in studies performed in partnership with health care systems may, under some situations, require precautions in addition to those regarding patient confidentiality, to protect specific interests of collaborating health care systems, facilities or providers. Precautions such as allowing data sharing in more supervised or restricted settings, such as access to researchers who agree to limited pre-approved research goals, may be appropriate to address these needs in implementing this data sharing policy.
3. Consistent with NIH policy and guidance, Collaboratory investigators will choose the least restrictive method for sharing of research data that provides appropriate protection for participant privacy, health system privacy, and scientific integrity.
4. Collaboratory investigators will work with NIH to implement this data sharing policy, to ensure the appropriate administrative processes and technical infra- structure are in place to support timely data sharing for the Collaboratory."

From: NIH Health Pragmatic Trials Collaboratory Data Sharing Policy

NIH Data Sharing Policy

"Key Points

1. This Policy applies to all human data in the NIH IRP, including the NIH Clinical Center as well as NIH Institutes and Centers.
2. A Data Sharing Plan (PDF File) must be developed for any research involving human data.
3. Data Sharing Plans will be included in the institute scientific review process for research involving human data.
4. The Institute Scientific Director (SD) or their designee is responsible for approving all Data Sharing Plans.
5. All IRP-supported clinical investigators are expected to develop protocols and consent processes/forms to enable broad data sharing for secondary research consistent with this Policy.
6. Sharing data for secondary research purposes shall comply with human subjects research regulations and procedures, if applicable.
7. All IRP investigators are encouraged to deposit data in publicly accessible research repositories for sharing to the extent feasible and appropriate.
8. This Policy is effective as of October 1, 2015. Any intramural research involving human data undergoing scientific review after October 1, 2015 must have a data sharing plan."

From the NIH Intramural Human Data Sharing Policy (updated December 2015). For more information, see NIH Data Sharing Policy and Implementation Guidance.

Medical Journal Data Sharing Requirements

The International Council of Medical Journal Editors (ICMJE) requires that 7 key elements be addressed in the data sharing statement:

1. "Will individual participant data be available (including data dictionaries)?
2. What data in particular will be shared?
3. What other documents will be available?
4. When will data be available (start and end dates)?
5. With whom will data be shared?
6. For what types of analyses will data be shared?
7. By what mechanism will the data be made available?"

From: International Council of Medical Journal Editors' Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals (updated December 2018).

Table 1 summarizes data sharing requirements of select academic journals and publishers to give researchers an idea of what may be required for publication.

Table 1. Data Sharing Requirements of Select Academic Journals and Publishers		
Journal/Publisher	**Requirements**	**Recommended Repository**
BMJ	Requires data from clinical trials to be made available upon request and requires a data sharing statement.	For clinical data, BMJ recommends controlled access repositories, such as clinicalstudydatarequest.com, the YODA project, or Vivli.
Elsevier	Encourages submission of a data paper, uploading data to a repository, or a data sharing statement stating why data can't be shared.	
Nature	Authors are required to make materials, data, code, and associated protocols promptly available to readers without undue qualifications. Restrictions on the availability of data must be disclosed upon submission.	Unstructured repositories like figshare and Dryad if no structured public repositories exist.
NEJM	Data sharing statement	Aligned with ICJME
PLOS	Data sharing statement	Dryad
Wiley	Data sharing statement	Mendeley Data

Examples from NIH Pragmatic Trials Collaboratory Demonstration Projects

NIH Collaboratory Demonstration Project investigators explored the risks to providers and health systems of sharing data. In Table 2 we describe the risks, the steps taken to mitigate the risks, and the data sharing structure that will be used for each of these pragmatic trials.

Table 2. NIH Pragmatic Trials Collaboratory Data Sharing Plans*			
Study name	**Risks to providers or health systems**	**Data sharing structure**	**Steps to mitigate risks to providers or health systems**
ABATE Active Bathing to Eliminate Infection	Data regarding infection rates could be used for inappropriate comparisons of facilities or with public reports. Detailed	Private enclave managed by study team	Potential users may propose specific queries. Only query results (not individual data) will be shared.

Table 2. NIH Pragmatic Trials Collaboratory Data Sharing Plans*			
	information regarding facilities and utilization patterns could reveal proprietary business information.		
ICD-Pieces **Improving Chronic Disease management with Pieces**	Data regarding patterns of care could be used for biased or inappropriate comparisons across facilities or health systems. Given different specifications, comparison to publicly reported quality measures would be misleading.	Private archive managed by NIDDK	Patient-level data will be de-identified and stored in aggregate database. Identifiers for healthcare system, primary practice and patients will be removed. Use of aggregate dataset will be governed by authorized agreements with NIDDK.
LIRE **Lumbar Image Reporting with Epidemiology**	Data regarding treatment patterns and resource use could be used for inappropriate or biased comparisons across health systems and could reveal proprietary health system business information.	Private archive managed by study team	Patient-level datasets will de-identified by health systems, clinics, providers, and patients. Investigators will authorize release to specific users for specific purposes.
PPACT **Pain Program for Active Coping and Training**	Data on opioid prescribing patterns could be misused for inappropriate comparisons of providers or facilities.	Public archive of a modified dataset	Public-use dataset will not include facility or health system identifiers, characteristics or prescribing/referral practices of individual providers, or patient-level data on race or ethnicity.
SPOT **Suicide Prevention Outreach Trial**	Data on suicide attempt rates could be used for biased or inappropriate comparisons of suicide attempts or suicide mortality across health systems.	Public archive of a modified dataset	Public-use dataset will not include indicator for health system.

Table 2. NIH Pragmatic Trials Collaboratory Data Sharing Plans*			
STOP CRC Strategies and Opportunities to Stop Colon Cancer in Priority Populations	Data on screening rates could be misused for inappropriate or biased comparisons of performance across clinics or inaccurate comparisons with public quality measures.	Private archive managed by study team	De-identified patient-level data will be available, with permissions and data use agreements in place. Data use agreements will limit to specific research uses and require destruction after authorized analyses are completed.
TiME Time to Reduce Mortality in End-Stage Renal Disease	Data regarding mortality could be misused for inappropriate or biased comparisons of facilities or healthcare systems. Detailed data regarding patterns of care could reveal proprietary business information.	Private archive managed by NIDDK	De-identified patient-level data that are aggregated across provider organizations will be stored at the NIDDK Central Repository. Facility identifiers, dialysis provider organization identifiers, and data elements that are unique to one of the dialysis providers will be removed. Data will be made available through formal request and a data use agreement between the requestor and the NIDDK.
TSOS Trauma Survivors Outcomes and Support	Data regarding baseline patient characteristics and study outcomes could be used for biased or inappropriate comparisons of care in participating facilities.	Private archive managed by study team	De-identified patient level data will be provided, with priority given to research that will effect trauma care systems nationwide and Collaboratory investigators.

*Assumes HIPAA-compliant patient de-identification for all patients and a data use agreement where appropriate.

Table from: Simon G, et al. Data Sharing and Embedded Research: Data Sharing Solutions for Embedded Research. In: *Rethinking Clinical Trials: A Living Textbook of Pragmatic Clinical Trials*. Bethesda, MD: NIH Pragmatic Trials Collaboratory. Available at: https://rethinkingclinicaltrials.org/chapters/dissemination/data-share-top/data-sharing-solutions-for-embedded-research/. Updated December 20, 2021. DOI: 10.28929/070.

Data Sharing Mechanisms

In Table 3, we describe different technical structures for data sharing and considerations that may assist researchers in selecting the appropriate mechanism for their trial. For more details, see the Living Textbook Chapter on Data Sharing.

Table 3. Technical Structures for Data Sharing From Least Restrictive (and Least Expensive) to Most Restrictive (and Most Expensive)

Structure	Description	Additional elements	Resource needs	Example
Public archive	Analyzable data can be obtained by any user for any use No restriction on the kinds of research questions new users can address	May impose restrictions like prohibitions against re-identification or access to small cell counts May de-identify certain elements, such as study site or demographics, or present sensitive data as an aggregate summary variable	Initial development and annotation Maintenance and access costs	Agency for Healthcare Research and Quality (AHRQ) Healthcare Cost and Utilization Project (HCUP)
Private archive	Analyzable data can be obtained by authorized users Honest broker or the original owner of the data decides which uses to authorize Requires binding agreement by recipient regarding protection and use of transferred data	As noted for public archive	As noted for public archive Evaluation of requests Execution of data sharing, data use, data transfer, and other agreements, including agree-ments covering data with full identifiers Monitoring of compliance with agreements, and response to breach of agreements	Yale University Open Data Access (YODA) Project Centers for Medicaid and Medicare (CMS) Limited Data Sets National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) Central Repository

Table 3. Technical Structures for Data Sharing From Least Restrictive (and Least Expensive) to Most Restrictive (and Most Expensive)				
Public enclave	Any user may query the data, but not take possession of it. Only aggregate results may be removed from the enclave No restriction on the kinds of questions users can address	May impose restrictions like prohibitions against re-identification, passing the data to other users, or access to small cell counts May de-identify certain elements, such as study site or demographics	Initial development and annotation Ongoing curation and governance Creation and maintenance of informatics support for analyses, including software licenses and computational capabilities, and file storage Personnel needed to ensure data quality, etc.	Centers for Medicare and Medicaid Services (CMS) Virtual Research Data Center (VRDC)
Private enclave	Similar to public enclave with regard to provisions for analyzing data without taking possession of it Honest broker or the original owner of the data decides which uses to authorize	Moderated by an honest broker or by representatives of the study and/ or site (either queries or results)	As noted for public enclave Additional resources to evaluate requests and supervise the conduct of approved studies	Food and Drug Administration (FDA) Sentinel Distributed Data Set

Table from: Simon G, et al. Data Sharing and Embedded Research: Data Sharing Solutions for Embedded Research. In: *Rethinking Clinical Trials: A Living Textbook of Pragmatic Clinical Trials*. Bethesda, MD: NIH Pragmatic Trials Collaboratory. Available at: https://rethinkingclinicaltrials.org/chapters/dissemination/data-share-top/data-sharing-solutions-for-embedded-research/. Updated December 20, 2021. DOI: 10.28929/070.

Examples of Data Sharing Platforms

There are many public and private data sharing platforms to choose from, and some will fit some projects more than others. In Table 4, we list and briefly describe some of them for informational purposes. Note that this list is not comprehensive nor is the Collaboratory mandating use of one of these platforms. This list represents possible platforms for consideration.

Table 4. Data Sharing Platforms

Platform	Description
clinicalstudydatarequest.com	Platform for sharing patient-level data
Dryad	A curated resource that makes the data underlying scientific publications discoverable, freely usable, and citable; provides a general purpose home for different data types
FAIRsharing	General data repository
figshare	Allows uploading of files up to 5GB in any file format and previewing of them in browser.
GitHub	Large code hosting platform; private, public, open source
HCUP	Agency for Healthcare Research and Quality (AHRQ) Healthcare Cost and Utilization Project
Mendeley Data	Certified, free-to-use repository that hosts open data from all disciplines, whatever its format (e.g., raw and processed data, tables, codes and software)
NIH Data Sharing Repositories	NIH supported data repositories that make data accessible for re- use. Most accept submissions of appropriate data from NIH- funded investigators (and others), but some restrict data submission to only those researchers involved in a specific network.
OSF	General data repository
re3data.org	Catalogues of registered and certified data repositories
Sentinel Distributed Data Set	Food and Drug Administration (FDA) Sentinel initiative (claims data)
Vivli	Global Clinical Research Data Sharing Platform
VRDC	Centers for Medicare and Medicaid Services (CMS) Virtual Research Data Center
YODA Project	A controlled access repository
Zenodo	General data repository

Examples of Data Sharing Statements

As previously described, the International Council of Medical Journal Editors (ICMJE) requires that 7 key elements be addressed in the data sharing statement. Below are example statements that that have been used to fulfill these requirements.

Suicide Prevention Outreach Trial (SPOT) Data Sharing Statement

"A deidentified version of the analytic dataset will be made available at the time of the initial publication of primary study findings. Consistent with policies of the NIH Collaboratory, all resources (intervention materials, specifications, computer code, etc.) will be shared at or before the publication of study results."

From: Simon GE, Beck A, Rossom R, Richards J, Kirlin B, King D, Shulman L, Ludman EJ, Penfold R, Shortreed SM, et al. 2016. Population-based outreach versus care as usual to prevent suicide attempt: study protocol for a randomized controlled trial. Trials. 17(1):452. doi:10.1186/s13063-016-1566-z.

NIH Pragmatic Trials Collaboratory Data Sharing Statement

Links to the de-identified data set as well as resources, such as the study protocol, consent documents, phenotypes and the data dictionary can be found at https://rethinkingclinicaltrials.org/data-and-resource-sharing/.

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Onboarding Data and Resource Sharing Questionnaire

Table of Contents

Data and Resource Sharing Questionnaire 1
Data and Resource Sharing Checklist 6

Data and Resource Sharing Questionnaire

This questionnaire is a worksheet to guide Demonstration Projects in developing data sharing plans that meet program requirements (see below checklist). This questionnaire is to be used as part of the onboarding process and can used for planning purposes by other researchers who need to share data.

Instructions/guidance are provided in italics. Please provide responses in the answer column.

Data Sharing Questionnaire **1. Study information**	
Question	**Answer**
What is the trial name and acronym?	
Who is completing this questionnaire?	
Date of questionnaire completion?	
Please provide a link to the trial's ClinicalTrials.gov registration.	

Prepared by: NIH Collaboratory Coordinating Center
Version: April 7, 2022

2. Data elements and sharing						
*NIH Pragmatic Trials Collaboratory investigators will each **share, at a minimum, a final research dataset** upon which the accepted primary pragmatic trial publication is based (from the NIH Collaboratory Data Sharing Policy; see Data Sharing Information Document for additional information from NIH Pragmatic Trials Collaboratory, NIH, and medical journal data sharing policies).*						
2a. Please describe all data collected/used for this study. Select all that apply and fill out each column as applicable.						
Data	**Y/N**	**If Y, brief description of data**	**Identifiable? If so, what IDs?**	**Can it be shared without restriction?**	**Can it be shared with restriction?**	**Describe restrictions** (e.g., IDs stripped, aggregated info only, etc.) **or reason data cannot be shared**
• Individual Level Data						
• Primary data collection through informed consent						
• Primary data collection through waiver of informed consent						
• Secondary data use – data collected by researchers of an earlier study						
• Secondary data use -- administrative data obtained from a covered entity (e.g., claims and assessment data from CMS; electronic health records from health care providers, etc.)						
• Other						
• Provider Level Data						
• Other Data (e.g., state policy, market level, Census)						

2b. Please describe the analytic dataset that will be released	
Will individuals be identifiable? _____Yes _____No _____ N/A	Comments/explanation:
Level of dataset: _____Individual _____Provider _____Other	Brief description of dataset:
If not identifiable, can individuals be differentiated? (e.g., includes a study-generated ID so that multiple events/observations can be attributed to a unique study participant) _____ Yes _____ No	Comments/explanation:
Will providers be identifiable? _____Yes _____No _____ N/A	If not identifiable, can providers be differentiated? _____ Yes _____No
Can the primary analyses be replicated using the released data? _____ Yes _____ No	If no, why not? (e.g., aggregated data; missing elements; etc.)
What value will the data have for other researchers?	

3. What precautions/risks need to be considered?	
The NIH Collaboratory Steering Committee recognizes that sharing data derived from clinical care in studies performed in partnership with healthcare systems may, under some situations, ***require precautions in addition to those regarding patient confidentiality****, to protect specific interests of collaborating healthcare systems, facilities, or providers. Precautions such as allowing data sharing in more supervised or restricted settings, such as access to researchers who agree to limited pre-approved research goals, may be appropriate to address these needs (from the NIH Collaboratory Data Sharing Policy).*	
Question	**Answer**
What precautions are needed other than those regarding patient confidentiality?	
Have your research partners expressed concerns about how the data will be shared (enclave, repository, etc.)?	
What are the risks to providers and health systems if a less restrictive mechanism is used? (See Data Sharing Information Document for examples from NIH Collaboratory Demonstration Projects.)	

4. How will the data be shared?	
*Consistent with NIH policy and guidance, NIH Pragmatic Trials Collaboratory investigators will choose the **least restrictive method for sharing of research data** that provides appropriate protection for participant privacy, health system privacy, and scientific integrity (from the NIH Collaboratory Data Sharing Policy).*	
Question	**Answer**
What is the least restrictive mechanism you can use for sharing data? (See Data Sharing Information Document for details about these mechanisms.) • Public archive (least restrictive) • Public enclave • Private archive • Private enclave (most restrictive)	
What specific platform will be used? (See Data Sharing Information Document for example data sharing platforms.)	

5. Preparing for data sharing	
Question	**Answer**
When will you share data? Prior to or after publication?	
Please write a draft data sharing statement. (See Data Sharing Information Document for example statements.)	
Do you foresee any obstacles regarding data and resource sharing?	

6. What resources will be shared?

*As part of the NIH Pragmatic Trials Collaboratory's commitment to sharing, all Demonstration Projects are expected to share data **and resources, such as protocols, phenotypes, videos, training materials, consent documents, and recruitment materials**. We recommend that elements of a final data sharing package include the items listed below. If an element will not be included in the data sharing package, please provide a brief explanation for the omission. Resources can be housed in the NIH Collaboratory Knowledge Repository (KR), on a repository (i.e., GitHub), or on a study website. We will link to the materials from the Living Textbook. To request posting of materials to the KR, contact nih-collaboratory@dm.duke.edu.*

Item	Will you publish? Yes, No, N/A If No, justify	Where publish (mark all that apply)		When publish (mark all that apply)		
		NIH KR	Other (specify)	Per manuscript*	Start of study	End of study
Final version of protocol						
Consent documents/process						
Computable phenotypes for outcome measures						
Computable phenotypes for inclusion/exclusion criteria						
Code for generating variables in the analytic dataset from standard sources						
Study questionnaires						
Annotated data collection forms						
Data dictionary (proc contents) for public use dataset						
Data dictionary (proc contents) for all data used in study with annotation regarding limitations on sharing each element						
Code for generating the tables present in a particular manuscript*						
Instructions on how to obtain data that were unable to be released (e.g., CMS data files)†						
Other						

*For example, PROVEN developed a process of submitting supplemental material for each manuscript published. They store the information in Brown's Digital Repository with a manuscript-specific URL that is published within the manuscript. They include the code that generated the manuscript's tables.
†For example, the PROVEN team refers the reader to www.resdac.org for the use of CMS data files and lets them know the file types and years used for its study since they cannot release those data.

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Data and Resource Sharing Checklist

Background

All NIH Pragmatic Trials Collaboratory Demonstration Projects will be expected to review this checklist as part of the onboarding process so they understand what will be expected. They will complete the checklist at closeout.

As part of the NIH Pragmatic Trials Collaboratory's commitment to sharing, all of its Demonstration Projects are expected to share data and resources, such as protocols, phenotypes, videos, training materials, consent documents, and recruitment materials. We recommend that elements of a final data sharing package include the items listed in the checklist below. If an element will not be included in the data sharing package, please provide a brief explanation for the omission. Resources can be housed in the NIH Collaboratory Knowledge Repository (KR), on a repository (i.e., GitHub), or on a study website. We will link to the materials from the Living Textbook on each project's Demonstration Project page and through a separate Data and Resource Sharing section. To request posting of materials to the KR, contact nih-collaboratory@dm.duke.edu.

Note: There will **not** be a dedicated space on the NIH Collaboratory website for posting analytic datasets; rather, we will post a hyperlink to the data sharing repository chosen by each project. In the Data Sharing Information Document, the EHR Core provides a partial list of existing data sharing platforms. The accompanying Data Sharing Information Document also contains information on data sharing requirements for the NIH Pragmatic Trials Collaboratory, NIH, and medical journals; information on data sharing mechanisms and platforms; and examples from Demonstration Projects.

Data and Resource Sharing Checklist for Plan Development – Part 1

Data and Resource Sharing Checklist
1. Study information
Trial name and acronym:
Checklist completed by:
Date:
Link to ClinicalTrials.gov registration:
Link to study website:

Data and Resource Sharing Checklist for Plan Development – Part 2

Data and Resource Sharing Checklist		
2. Resource location		
Item	**Provide hyperlink or indicate if item will be stored in the KR**	**If item will not be shared, please provide a brief explanation for the omission**
Publications		
Link to protocol paper		
Link to main outcome paper		
Link to other study-related publications		
Study tools		
Final version of the protocol, including summary of changes		
Consent documents or consent process		
Computable phenotypes for outcome measures		
Computable phenotypes for the inclusion/exclusion criteria		
Code for generating variables in the analytic dataset from standard sources		
Datasets and documentation		
Annotated data collection forms		
Link to public use dataset		
Data dictionary (proc contents) for public use dataset		
Other resources		

Closeout Data and Resource Sharing Checklist

Purpose

As part of the NIH Pragmatic Trials Collaboratory's commitment to sharing, all Demonstration Projects are expected to share data and resources, such as protocols, phenotypes, videos, training materials, consent documents, and recruitment materials. We recommend that elements of a final data sharing package include the items listed in the checklist below. If an element will not be included in the data sharing package, please provide a brief explanation for the omission. Resources can be housed in the NIH Collaboratory Knowledge Repository (KR), in a repository (i.e., GitHub), or on a study website. We will link to the materials from the Living Textbook. To request posting of materials to the KR, contact nih-collaboratory@dm.duke.edu.

Note: There will **not** be a dedicated space on the NIH Collaboratory website for posting analytic datasets; rather, we will post a hyperlink to the data sharing repository chosen by each project. In the Data Sharing Information Document, the EHR Core provides a partial list of existing data sharing platforms. The accompanying Data Sharing Information Document also contains information on data sharing requirements for the NIH Pragmatic Trials Collaboratory, NIH, and medical journals; information on data sharing mechanisms and platforms; and examples from Demonstration Projects.

Data and Resource Sharing Checklist

All NIH Pragmatic Trials Collaboratory Projects are expected to complete this checklist at closeout. The information provided in the checklist will be published in the Living Textbook on each Demonstration Project's page and on a Data and Resource Sharing page.

Data and Resource Sharing Checklist		
1. Study information		
Trial name and acronym:		
Checklist completed by:		
Date:		
Link to ClinicalTrials.gov registration:		
Link to study website:		
2. Resource location		
Item	**Provide hyperlink or indicate if item will be stored in the KR**	**If item will not be shared, please provide a brief explanation for the omission**
Publications		
Link to protocol paper		
Link to main outcome paper		
Link to other study-related publications		
Study tools		
Final version of the protocol, including summary of changes		
Consent documents or consent process		
Computable phenotypes for outcome measures		
Computable phenotypes for the inclusion/exclusion criteria		
Code for generating variables in the analytic dataset from standard sources		
Datasets and documentation		
Annotated data collection forms		
Link to public use dataset		
Data dictionary (proc contents) for public use dataset		
Other resources		

ABSTRACTS

UG3 Project: Adapting and Implementing a Nurse Care Management Model to Care for Rural Patients with Chronic Pain (AIM-CP)

Co-Principal Investigators:

- Sebastian Tong, MD, MPH
- Kushang Patel, PhD, MPH

Sponsoring Institution: University of Washington

Collaborators:

- WWAMI (Washington, Wyoming, Alaska, Montana, and Idaho) region Practice and Research Network
- Mecklenburg Area Partnership for Primary Care Research in rural North Carolina

NIH Institute Providing Oversight: National Institute of Nursing Research (NINR)

Program Official: Karen Kehl, PhD, RN, FPCN (NINR)

Project Scientist: Alexis Bakos, PhD, MPH, RN (National Institute on Aging [NIA])

Abstract:

Chronic pain affects over 20% of the U.S. adult population and frequently has debilitating effects on quality of life and physical and mental functioning. Individuals living in rural communities experience higher rates of chronic pain as well as poorer health outcomes because of pain. The 46 million Americans who live in rural areas frequently lack access to evidence-based, non-pharmacologic treatments for chronic pain. As such, a critical need exists to implement effective, comprehensive programs for pain management that include non- pharmacologic treatment options. Nurse care management (NCM) has been successfully used to enhance care for individuals with other chronic conditions or at high risk of complications. Using a type 2 hybrid effectiveness-implementation design, we propose to adapt, pilot, and implement a NCM model that includes care coordination, cognitive behavioral therapy (CBT), and referrals to a remotely delivered exercise program for rural patients with chronic pain. Each health system will identify appropriate health care professionals to be trained as care managers. For the CBT component, care managers will be trained to engage patients in a remotely delivered CBT program. For exercise, we will offer remotely delivered Enhance Fitness, which is an evidence-based, 16-week program that includes aerobic and strength training exercise. In the UG3 phase, we will engage patients, clinicians, and care managers from 2 health systems serving rural patients in a learning collaborative to pilot the NCM model. In addition, we will adapt infrastructure and workflows to implement the intervention program and engage the partnering health systems in developing relationships with community partners and identifying care managers. In the UH3 phase, we will conduct a randomized controlled trial of the adapted NCM model versus usual care in rural dwelling patients with chronic pain. We have recruited 6 health systems from 2 practice-based research networks, the WWAMI (Washington, Wyoming, Alaska, Montana, and Idaho) region Practice and Research Network and the Mecklenburg Area Partnership for Primary Care Research in rural North Carolina. Our primary outcome is pain interference as measured by the Pain, Enjoyment of Life and General Activity (PEG) scale. Our secondary outcomes include physical function, sleep, pain catastrophizing, depression, anxiety, treatment satisfaction, substance use disorder, pain medication use/dosage including opioids, and health care utilization. We will explore if disparities exist by

examining heterogeneity in treatment effects via subgroup analyses by age, gender, race/ethnicity, and health insurance. We will use the RE-AIM framework to assess implementation outcomes and qualitative interviews conducted with a subset of patients to evaluate experiences with the intervention. If successful, this study will have a transformative effect on chronic pain management in rural areas by expanding access to evidence-based, non-pharmacologic treatments through an innovative NCM model.

NIH Project Information

UG3 Project: Advancing Rural Back Pain Outcomes through Rehabilitation Telehealth (ARBOR-Telehealth)

Co-Principal Investigators:

- Richard L. Skolasky Jr., ScD, MA
- Kevin McLaughlin, DPT

Sponsoring Institution: Johns Hopkins University

Collaborators:

- TidalHealth

NIH Institute Providing Oversight: National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)

Program Official: Charles Washabaugh, PhD (NIAMS)

Project Scientist: TBD

Abstract:

Chronic low back pain (LBP) imposes tremendous burden on affected individuals, healthcare systems, and society. LBP has been identified as the most common cause of disability globally and in the United States (US). LBP is also the largest driver of US healthcare spending ($135 billion in 2016) and the most common diagnoses associated with opioid prescription and consumption. For patients with chronic LBP, physical therapy has been shown to be a cost-effective method for improving pain and disability. In addition, physical therapy has been shown to decrease the risk of advanced imaging, injections, surgery, and opioid use in patients with chronic LBP. Despite available evidence in support, only 7-13% of patients with LBP, including those with chronic LBP, go on to receive physical therapy services, with patients reporting barriers accessing physical therapy, such as transportation, provider availability and missed work time. Access is especially limited in rural communities where there are approximately 40% fewer physical therapists available per capita compared to metropolitan regions. In addition, patients living in rural communities likely need to travel longer distances to receive physical therapy, requiring additional missed work time and transportation costs. This lack of access to physical therapy in rural communities likely contributes to the greater rates of LBP-related disability and opioid consumption that have been observed in rural communities compared to metropolitan areas. Innovative methods for improving access to physical therapy are urgently needed to address disparities in outcomes for patients with chronic LBP living in rural communities in the US. Telehealth has rapidly expanded during the COVID-19 pandemic. This includes policy changes that have allowed physical therapists to begin providing care remotely, also referred to as telerehabilitation. Telerehabilitation stands to improve access to physical therapy for patients with chronic LBP living in rural communities and may serve as a means of improving outcomes of these patients. We will conduct a single-blind prospective randomized clinical trial addressing key questions to understanding the effectiveness of a risk-stratified telerehabilitation to reduce opioid use and LBP-related disability and to improve physical function and health-related quality of life (HRQoL) in patients with chronic LBP. Additionally, we will explore implementation outcomes using a mixed methods approach consisting of electronic surveys and semi-structured interviews with patients, physical therapists, practice managers, and outpatient services administration focusing on perceived quality and impact on

barriers to care. We will enroll 434 patients with LBP presenting to primary care clinics serving rural communities (TidalHealth, Salisbury, MD). Eligible patients will provide informed consent and be randomized to either an educational control or risk-stratified telerehabilitation (low-risk, remote therapeutic monitoring; medium-risk, physical therapy telehealth visits; or high-risk, psychologically informed physical therapy telehealth visits). Primary effectiveness outcome is difference in change in LBP-related disability (Oswestry Disability Index) and in opioid use after 8 weeks of treatment.

NIH Project Information

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UG3 Project: I CAN DO Surgical ACP (Improving Completion, Accuracy, and Dissemination Of Surgical Advanced Care Planning) Trial

Co-Principal Investigators:

- Elizabeth Wick, MD
- Genevieve Melton-Meaux, MD, PhD
- Rebecca Sudore, MD

Sponsoring Institution: University of California, San Francisco

Collaborators:

- University of California, San Francisco (UCSF)
- University of California, Irvine (UCI)
- University of Minnesota (UMN, clinical site of M Health Fairview, a collaboration of the Univ. of MN Medical School, Univ of MN Physicians, and Fairview Health Services)

NIH Institute Providing Oversight: National Institute on Aging (NIA)

Program Official: Barbara Radziszewska, PHD, MPH (NIA)

Project Scientist: Marcel Salive, MD, MPH (NIA)

Abstract:

Nearly 20 million older adults undergo major elective surgical procedures, yet very few receive advance care planning (ACP). This is a critical missed opportunity to ensure optimal and patient-aligned medical decisions and communications. Despite ACP being incorporated into national quality metrics and society guidelines for surgical care for older adults, there are few examples of effective integration into the pre-surgical phase. Efforts to date have mostly focused on improving surgeons' use of ACP but barriers remain significant, including varying levels of familiarity and comfort to conduct ACP conversations, lack of dedicated time during the pre-surgical care episode for these often-delicate conversations, and lack of appropriate patient-facing ACP tools to help patients and caregivers make complex decisions about their surgical treatment. Our team has designed and tested a theory-based, interactive ACP patient-facing technology solution (PREPARE) based on the new ACP paradigm of preparing people for communication and medical decision-making. Despite consistent evidence that PREPARE increases ACP engagement and patient and clinician empowerment to discuss ACP, a gap remains in extending PREPARE's use to pre-surgical populations. We hypothesize that by including PREPARE into the electronic health record (HER)-centric pre-surgery workflow for older adults and including automated reminders, we can empower patients and surgical teams to engage in ACP discussions. Given the limited time and resources in the surgical setting to conduct ACP, we will be testing 3 delivery strategies in increasing resource intensity (PREPARE alone, PREPARE with text/phone reminders, or the additional of a healthcare navigator). To ensure generalizability, we will conduct our work in 3 healthcare systems (HCS): Univ. of CA, San Francisco (UCSF), Univ. of CA, Irvine (UCI) and M Health Fairview (UMN, a collaboration among the Univ. of MN Medical School, Univ of MN Physicians, and Fairview Health Services). We will first establish trial infrastructure (UG3) to conduct (UH3) an NIH Stage Model III (efficacy-effectiveness) three arm RCT in 3 HCS. Patients aged 65 or older, or with serious illness, who are referred for major elective surgery will be randomized to Arms: (1) Letter about ACP, PREPARE advanced directive (AD),

PREPARE website; (2) Letter, AD, PREPARE plus reminder text/phone messages; (3) Letter, AD, PREPARE plus reminders plus a healthcare navigator on ACP documentation (discussions and care plans, primary outcome) and patient-reported ACP engagement. Using mixed methods, we will assess patients' and surgical care teams' experience with surgery ACP. ACP note content will be evaluated using natural language processing (NLP) and data mining to begin to identify assess thematic completeness of ACP notes. This work is innovative because we are coalescing existing collaborations between HCS into a transdisciplinary group of surgeons, geriatricians, and informaticians to develop infrastructure and rigorously test a novel patient-centered system-level approach to integrating ACP into the surgical care episode, the first step towards goal-concordant surgical care.

NIH Project Information

R01: Implementing Scalable, PAtient-centered Team-based Care for Adults with Type 2 Diabetes and Health Disparities (iPATH)

Principal Investigator:

- Sara Singer, PhD, MBA

Sponsoring Institution: Stanford University

Collaborators:

- Harvard University
- Ohio State University
- Impactivo, LLC

NIH Institute Providing Oversight: National Institute on Minority Health and Health Disparities (NIMHD)

Program Official: Lynne Slaughter Padgett, PhD, FAPOS (NIMHD)

Abstract:

A collaborative network of research teams from Stanford, Harvard, The Ohio State University, and Impactivo, LLC propose practice-relevant research focused on diabetes care in federally qualified health centers (FQHCs). Some 37.3 million Americans have type 2 diabetes and significant racial and socioeconomic disparities persist in care quality and patient safety. FQHCs serve 1 in 7 U.S. racial/ethnic minorities and shoulder a higher prevalence of diabetes (21% FQHC, 11% U.S.), offering a promising venue for innovating in equity-focused diabetes care. The iPATH project will refine and implement an approach to practice transformation originally conceived to support FQHCs' pursuit of National Committee for Quality Assurance recognition as patient-centered medical homes. A pilot demonstrated significant decreases (average 31% reduction) in poorly controlled diabetes (A1c>9%) among patients at 7 clinics affiliated with an FQHC in Puerto Rico in 2017-20. Improvements in patients' diabetes control were sustained pre- to post- Covid-19 pandemic. Aim 1. Refine the iPATH implementation approach by identifying organizational conditions and processes at FQHCs that promoted or impeded the effectiveness of type 2 diabetes care for NIH- designated U.S. health disparity populations pre- and post-pandemic. Research teams will simultaneously conduct 12 in-depth regional case studies, enabling contrast between FQHCs considered high- performing and low-performing for diabetes control. Teams will identify actionable, how-to implementation factors for ensuring chronic, preventive, and acute care for patients with diabetes. Employing an innovative Rapid Data Collection and Reporting methodology, teams will rapidly collect, analyze, and share data to accelerate dissemination of customized feedback to FQHC leaders and to inform adaptation and implementation of the iPATH practice transformation. Aim 2. Implement a multi-level, multi-component, technology-enabled practice transformation strategy to improve type 2 diabetes for patients at 8 multi-clinic FQHCs. Teams will adapt, tailor, implement, test, and spread an equity-focused practice transformation strategy across FQHCs located in California, Massachusetts, Ohio, and Puerto Rico. The iPATH implementation approach will be modularized and customizable to accommodate organizational readiness, patient needs, and social contexts, tailoring practice transformation efforts to each unique FQHC. Aim 3. Comprehensively evaluate the iPATH implementation approach with a hybrid type 2 study, including a stepped wedge cluster randomized trial. Including formative, process, and summative evaluation elements guided by the Exploration-Preparation-Implementation-Sustainment model, the study will evaluate impact of practice transformation and identify process elements affecting implementation effectiveness. Analyses will leverage FQHC data by race and ethnicity to examine health disparities.

NIH Project Information

R01: Maternal OutcoMes (MOMs) Program: Testing Integrated Maternal Care Model Approaches to Reduce Disparities in Severe Maternal Morbidity

Co-Principal Investigators:

- Stephanie L. Fitzpatrick, PhD

Sponsoring Institution: Feinstein Institute for Medical Research

Collaborators:

- Northwell Health

NIH Institute Providing Oversight: National Institute of Nursing Research (NINR)

Program Official: Shalanda Bynum, PhD, MPH (NINR)

Abstract:

There is a maternal health crisis in the United States that disproportionately affects Black birthing people. Black birthing people are two times more likely to experience severe maternal morbidity (SMM) - "unexpected outcomes of labor and delivery that result in significant short- or long-term consequences to a birthing person's health" – than non-Hispanic White birthing people. Preventing preeclampsia, increased or maintained engagement in healthy behaviors (e.g., physical activity), and support addressing health-related social needs can enhance receipt of timely, appropriate care and reduce risk for SMM. The Maternal OutcoMes (MOMs) Program implemented at Northwell Health is an effective integrated care approach that identifies and supports high-risk birthing people immediately post-delivery. In preliminary analysis based on data from 2500 participants, the MOMs Program significantly reduced risk for SMM-related hospital admissions 30-days post-delivery by 77% among Black participants. These preliminary findings are promising; however, the long-term effectiveness needs to be established as well as the feasibility and effectiveness of extending the MOMs Program to the prenatal period.

The purpose of this study is to test the effectiveness of an integrated care model approach at two different levels of intensity designed to facilitate timely, appropriate care for high-risk Black birthing people and reduce risk for SMM. Black birthing people with an Obstetrics-Comorbidity Index Score ≥ 3 and/or a history of pre-eclampsia will be identified via the electronic health record and 674 will be recruited and randomized during the first trimester to one of two study arms: MOMs High-Touch (MOMs-HT) vs. MOMs Low-Touch (MOMs-LT). MOMs-HT will consist of close clinical and behavioral health monitoring via chatbot technology and navigation to timely care and services by the MOMs team throughout the prenatal and postpartum periods; 12 bi-weekly self-management support calls with the MOMs team during the prenatal period; and 4 weekly postpartum clinical check-in calls with navigation by the MOMs team immediately post-delivery. MOMs-LT will also include clinical and behavioral health monitoring via the chatbot along with navigation to services by the MOMs team and 4 weekly postpartum clinical check-in calls with navigation. The two study arms will be compared on incidence of SMM at labor and delivery (Aim 1), incidence rate of SMM-related hospitalizations at 1-month and 1-year postpartum (Aim 1a), time to preeclampsia diagnosis and initiation of treatment (Aim 2), change in perceived social support domains (Aim 3), and physical activity trajectories (exploratory Aim 4). Findings from this study will help to determine how to feasibly implement an effective and sustainable integrated care approach to address SMM disparities.

NIH Project Information

UG3 Project: Reaching Rural Veterans: Applying Mind-Body Skills for Pain Using a Whole Health Telehealth Intervention (RAMP)

Co-Principal Investigators:

- Diana Burgess, PhD
- Roni L. Evans, DC, MS, PhD
- Katherine E. Hadlandsmyth, PhD

Sponsoring Institution: Center for Veterans Research and Education

Collaborators:

- Minneapolis VA Healthcare System
- University of Minnesota
- University of Iowa

NIH Institute Providing Oversight: National Institute of Nursing Research (NINR)

Program Official: Karen Kehl, PhD, RN, FPCN (NINR)

Project Scientist: Lanay Mudd, PhD National Center for Complementary and Integrative Health (NCCIH)

Abstract:

This project addresses the significant challenge of implementing effective, non-opioid interventions for chronic pain management in rural and remote dwelling Veteran populations. Pain is now widely recognized as a complex biophysical, psychological, and social (BPS) condition. There is also a growing evidence base to support several complementary and integrative health (CIH) approaches, to address pain in a more holistic way. While the Veterans Administration (VA) has become a leader in advancing CIH through its Whole Health Initiative, there remain many barriers, especially for rural patients with pain.

The Reaching Rural Veterans: Applying Mind-Body Skills for Pain (RAMP) project aims to overcome these barriers. Our team is working with multiple levels of VA stakeholders (including rural patients), to develop an innovative telehealth evidence-based intervention, RAMP, that is cohesive and strategically coalesces multiple evidence based CIH self-management strategies to address Veterans' BPS needs.

Designed to be implemented within the VA through its nationwide Whole Health System initiative, RAMP is a 12-week program. It includes a 1-to-1 session with a Whole Health Coach, followed by 11 group sessions including pre-recorded expert-led education videos, mind-body skill training and practice, and group discussions. Program content covers pain education, mindfulness, pain specific exercises, and cognitive behavioral strategies.

For the preparatory phase (UG3) we will: 1) conduct stakeholder engagement activities including identifying and developing new community partnerships and using mixed methods data collection from multiple levels of stakeholders (n=35-50 patients, community partners, VA healthcare system leaders and staff), guided by the established RE-AIM/PRISM framework, to learn about key factors that can affect long-term adoption; and 2) conduct a pilot study of 40

rural VA patients with chronic pain to assess the feasibility of delivering RAMP (experimental intervention for the UH3 trial) in terms of recruitment and engagement, intervention fidelity and adherence, data collection, and other key metrics.

For the future UH3 Phase, we will conduct a randomized hybrid type 2 effectiveness-implementation multi-site pragmatic clinical trial of RAMP compared to usual care, among rural patients (n=500) in the VA healthcare system. UH3 Aim 1 will assess the relative effectiveness of RAMP in terms of the primary effectiveness outcome of pain interference at 13 and 26 weeks and secondary outcomes including opioid use and other HEAL recommended outcomes. In UH3 Aim 2 we will work iteratively with multiple levels of stakeholders (identified in the UG3) to evaluate intervention implementation strategies used in the trial and adapt these strategies to scale up RAMP within the national VA healthcare system. This will include: a) conducting mixed-methods assessments of stakeholder and trial participant views of implementation-related barriers and facilitators, resource needs, and other RE-AIM/PRISM domains; b) working with stakeholders to co-create additional plausible strategies for overcoming barriers to implementation of RAMP; and c) conducting budget impact analyses using models informed by stakeholder views to inform future decision making.

NIH Project Information

BARRIERS SCORECARDS

AIM-CP: Barriers Scorecard

Barrier	Level of Difficulty*				
	1	2	3	4	5
Enrollment and engagement of patients/subjects				X	
Engagement of clinicians and health systems		X			
Data collection and merging datasets			X		
Regulatory issues (IRBs and consent)			X		
Stability of control intervention		X			
Implementing/delivering intervention across healthcare organizations			X		

*Your best guess!
1 = little difficulty
5 = extreme difficulty

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ARBOR-Telehealth: Barriers Scorecard

Barrier	Level of Difficulty*				
	1	2	3	4	5
Enrollment and engagement of patients/subjects				X	
Engagement of clinicians and health systems			X		
Data collection and merging datasets			X		
Regulatory issues (IRBs and consent)		X			
Stability of control intervention			X		
Implementing/delivering intervention across healthcare organizations				X	

*Your best guess!
1 = little difficulty
5 = extreme difficulty

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I CAN DO Surgical ACP: Barriers Scorecard

Barrier	Level of Difficulty*				
	1	2	3	4	5
Enrollment and engagement of patients/subjects		X			
Engagement of clinicians and health systems			X		
Data collection and merging datasets				X	
Regulatory issues (IRBs and consent)		X			
Stability of control intervention			X*		
Implementing/delivering intervention across healthcare organizations				X*	

*Your best guess!
1 = little difficulty
5 = extreme difficulty

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iPATH: Barriers Scorecard

Barrier	Level of Difficulty*				
	1	2	3	4	5
Enrollment and engagement of patients/subjects			X		
Engagement of clinicians and health systems				X	
Data collection and merging datasets				X	
Regulatory issues (IRBs and consent)				X	
Stability of control intervention	N/A				
Implementing/delivering intervention across healthcare organizations	N/A				

*Your best guess!
1 = little difficulty
5 = extreme difficulty

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MOMs: Barriers Scorecard

Barrier	Level of Difficulty*				
	1	2	3	4	5
Enrollment and engagement of patients/subjects	X				
Engagement of clinicians and health systems	X				
Data collection and merging datasets		X			
Regulatory issues (IRBs and consent)		X			
Stability of control intervention			X		
Implementing/delivering intervention across healthcare organizations	X				

*Your best guess!
1 = little difficulty
5 = extreme difficulty

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RAMP: Barriers Scorecard

Barrier	Level of Difficulty*				
	1	2	3	4	5
Enrollment and engagement of patients/subjects		X			
Engagement of clinicians and health systems		X			
Data collection and merging datasets	X				
Regulatory issues (IRBs and consent)		X			
Stability of control intervention	n/a				
Implementing/delivering intervention across healthcare organizations		X			

*Your best guess!
1 = little difficulty
5 = extreme difficulty

NIH PRAGMATIC TRIALS COLLABORATORY
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DATA AND RESOURCE SHARING PLANS

NIH PRAGMATIC TRIALS COLLABORATORY
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Adapting and Implementing a Nurse Care Management Model to Care for Rural Patients with Chronic Pain (AIM-CP)

RESOURCES AND DATA SHARING PLAN

Principal Investigators: Sebastian Tong, MD, MPH; Kushang Patel, PhD, MPH

Resources

The University of Washington (UW) research team will co-lead development of all policies, practices, materials, and tools for facilitating data collection and sharing to target facilitation of collaboration between Co-I's, reuse data, and replication of the project. All members of the research team will abide by the UW IRB and the NIH HEAL Initiative Public Access and Data Sharing requirements (https://heal.nih.gov/about/public-access-data).

Data Sharing Plan

Electronic Health Record (EHR) Data Privacy and Confidentiality. The UW will serve as the data coordinating center for all EHR data involved in the trial. The UW team has extensive experience with data access, privacy protection, and management. All health care system partners will de-identify data, removing PHI, except for service dates and year of birth, before sending data extractions to the University of Washington (UW) research team for analyses. UW will facilitate secure transfer of the data from the health care systems to a HIPAA compliant computing environment supported by the Department of Family Medicine and the Institute of Translational Health Sciences. All data sharing protocols will be IRB approved by the single IRB governance provided by UW. Each health care system partner will also complete a Data Use Agreement to support use of their EHR data for the trial and any defined ancillary studies deemed to be in scope by the Co-PIs. Any data shared out with other partnered institutions in support of completing ancillary studies will be done through a clear data management plan and technical infrastructure for rigorous data handling and safety monitoring, led by the UW team and vetted through the UW IRB.

We will prepare and share a final research data set that the accepted primary pragmatic trial publication is based upon. The final data set will be structured to maximize future scientific value while protecting patient and health system privacy. The UW research team will remove or de-identify all of the 18 HIPAA-specified direct identifiers in the final dataset. The aim of our data sharing policy is to strive for the least restrictive plan possible while providing appropriate protection for participant privacy, health system privacy, and scientific integrity.

The final research data set will be stored separately from the operational study database in a secure HIPAA compliant database platform, where access and downloads can be easily monitored and the data are downloadable securely by the research analytics team at UW in a variety of formats (Excel, R, SAS, Stata, SPSS). A comprehensive data dictionary will be available alongside the final research database. The data sharing plan will be executed within the final year of funding. The overhead required to support this data sharing plan is minimal and therefore no additional budget is requested to cover its costs.

Within 9 months of the end of the final year of funding, a final study data set will be accessible via a supervised private data enclave. Access will be limited to registered users who submit proposed specific questions or analysis plans and sign a data use agreement. "Supervised" indicates that individual requests are reviewed to protect the intellectual property rights of the project investigative team by restricting external development of manuscripts using the study data that substantially overlap with those that are already in development by study investigators. We will form a publications committee, with investigator representatives from core research sites to establish manuscript development and publication guidelines.

Qualitative Data Privacy and Confidentiality. These data will include surveys, interviews, and field notes that will be stored securely at OHSU in accordance with IRB protocol and de-identified from name identifiers. Voice recordings will be stored in HIPAA compliant servers, where they will be transcribed for the qualitative team's analyses efforts. Raw qualitative data with identified voices and names will not be shared beyond the OHSU research team.

Consistency with HEAL Initiative Public Access and Data Sharing Policy

Our data coordinating center has previously worked on NIH Collaboratory studies and is budgeted to include work to meet all data sharing requirements. We will work with NIH staff to ensure that our data sharing plan meets HEAL Public Access and Data Sharing Policies, that our data meets FAIR principles and that we submit required forms to the HEAL Clinical Data Elements Program. We have chosen primary and secondary outcomes that are in concordance with the HEAL Clinical Data Elements Program to better facilitate this transfer of data.

Academic Presentation and Publications

Sharing of data generated by this project is an essential part of our proposed activities and will be carried out in several different ways. We plan to make our results available both to the community of scientists interested in improving chronic pain management in primary care settings to avoid unintentional duplication of research. Conversely, we would welcome collaboration with others who could make use of the findings, materials and resources developed in the study. Below are several ways we expect to specifically share data.

Presentations at national scientific meetings. It is expected that the Co-PIs and Co-Is will spearhead national conference presentations throughout the project to present works in progress, methods, and final outcome analyses. In addition, we will share methods and insights at meetings of the NIH Collaboratory. We also anticipate participating in the NIH Dissemination and Implementation Annual Conference and other relevant conferences sponsored by organizations with interest in the trial (e.g., Society for Behavioral Medicine, Academy Health, North American Primary Care Research Group).

Publications and Release of Data. All efforts will be made to rapidly release data through publication of results in peer reviewed journals as quickly as it is possible to analyze the outcomes of the study. Data used in publications will be released publicly in a timely manner. This project will generate data about chronic pain management from the participating health care systems. It is our explicit intention that these data will be placed in a readily accessible public database with health care system identifiers removed.

Community partners. We will work with our community partners as well as the WPRN and MAPPR to share results from our study.

NIH PRAGMATIC TRIALS COLLABORATORY
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Advancing Rural Back Pain Outcomes through Rehabilitation Telehealth (ARBOR-Telehealth)

DATA SHARING AND MANAGEMENT PLAN

Principal Investigators: Richard L. Skolasky Jr., ScD, MA; Kevin McLaughlin, DPT

The Research Team at the Johns Hopkins University and TidalHealth (sub-award) for the proposal titled "Improving Function and Reducing Opioid Use for Patients with Chronic Low Back Pain in Rural Communities through Improved Access to Physical Therapy using Telerehabilitation" (RFA-NR-23-001) agree to accept the overall governance, common protocols, publication policies, collaborative procedures, confidentiality, and data sharing plans to be developed by the HEAL Consortium. The following document exists to reflect our best practices for data acquisition, management, stewardship, and dissemination that are consistent with the HEAL Initiative Public Access and Data Sharing Policy.

DATA TYPE

Data generated by the scientific projects will include experimental and observational data, statistical and programming code, derived and compiled metadata, experimental and analytic documentation, and physical collections of specimens, images, and behavioral recordings.

Richard L. Skolasky, Sc.D. and Kevin McLaughlin, D.P.T. will work with leaders of each of the scientific projects at Johns Hopkins University (JHU) School of Medicine and TidalHealth to identify the type and amount/size of scientific data expected to be collected and used.

A description of which scientific data from the project will be preserved and shared.

The proposed project has the following aims:

1. Examine the effectiveness of risk-stratified telerehabilitation in reducing LBP-related disability among patients living in rural communities with chronic LBP. We will compare 4-month changes in LBP-related disability (measured using the Oswestry Disability Index [ODI]) between patients receiving telerehabilitation and usual care. Key secondary outcomes will include 4-month changes in physical function measured by the Patient Reported Outcome Measurement Information System (PROMIS)-29.
2. Compare the prevalence of opioid use between patients receiving risk-stratified telerehabilitation and educational control . We will use a combination of patients surveys and EHR data to assess opioid use in both groups at 4 and 12-months. Secondary outcomes will include other LBP-related healthcare utilization (e.g., physician office visits, imaging, surgery).
3. Compare effectiveness of Aims 1 and 2 in pre-defined patient groups by examining heterogeneity of treatment effect in pre-defined groups based on gender, risk stratification, and current opioid use.
4. Examine the implementation of risk-stratified telerehabilitation at a rural HCS by examining the acceptability, adoption, feasibility, and fidelity of our treatment approach guided by the RE-AIM framework. We will use a mixed-methods approach to accomplish this aim that incorporates patient and provider surveys, semi- structured interviews, focus groups, and key process metrics.

Project Aims 1, 2, and 3 will make use of data collected from the electronic medical record (EMR) at the participating health system (TidalHealth, Salisbury, MD) (e.g., diagnosis and problem list ICD10 codes and opioid prescription) and through participant self-report (e.g., LBP-related disability, opioid use). Project Aim 4 will make use of data collected from participant and provider surveys and semi-structure interviews (e.g., survey of perceived advantages/disadvantages) and from key process metrics (e.g., treatment initiation and retention and number of key components delivered). The table below details the data that will be collected in the proposed project.

Table 1. Assessment Schedule

Variable	Suggested Measure/Source	Item[1]	Base[2]	8 wk[2]	16/52 wk[2]
Predisposing Factors					
Socio-demographic[†,‡]	Age, Gender, Race/Ethnicity	6	ü		
Social support[†]	Marital/Partner Status	2	ü		
Cognitive[†]	Psychosocial Risk (SBST)	22	ü		
Enabling Factors					
Education/Economic[†]	Education, Income, Occupation	3	ü		
Insurance[†,‡]	Coverage	2	ü		
Need Factors					
Co-morbidities[†,‡]	Elixhauser Comorbidity Index (CCI)	19	ü		
Medical History[†,‡]	Pain Medications; Past Treatment	8	ü		
Health Habits[†]	Smoking, Alcohol Use, BMI (height & weight)	4	ü		
Effectiveness Outcomes (UG3 Aim 1)					
Disability[†]	**Oswestry Disability Index (ODI) (Primary)**	10	ü	ü	ü
Physical function[†]	PROMIS 29, v2.0 Physical Function (Secondary)	5	ü	ü	ü
Pain intensity[†]	Numeric Pain Rating Scale (NPRS) (Exploratory)	3	ü	ü	ü
Quality of Life[†]	PROMIS 29, v2.0 Profile (Exploratory)	29	ü	ü	ü
Health Use Outcomes (UG3 Aim 2)					
Opioid Use[†,‡]	Current opioid use for low back pain	2	ü	ü	ü
Health Care Use[†,‡]	Physical therapy (external to trial), Physician/ED visit, Imaging, Pain interventions, Medications, Back surgery	6	ü	ü	ü
Implementation Outcomes (UG3 Aim 4)					
Acceptability	Interest in study participation, Refusal reason	N/A	ü		
Adoption	Survey of perceived advantages/disadvantages	N/A	ü	ü	
Feasibility[‡]	Treatment initiation and retention	N/A	ü	ü	
Fidelity[‡]	Number of key components delivered	N/A		ü	
Safety					
Safety[*,**]	Adverse Events	N/A	ü	ü	ü

[†] Data provided through patient self-report
[‡] Data provided through passive EHR collection
[1] Number of items that participants must complete
[2] All assessments conducted over telephone or using emailed link to REDCap project

A brief listing of the metadata, other relevant data, and any associated documentation (e.g., study protocols and data collection instruments) that will be made accessible to facilitate interpretation of the scientific data.

Documentation will consist at the level of the project aim (e.g., research strategy and regulatory documents) and the individual experiment level (e.g., lab manual describing experimental controls, methods, and outcomes) and the analytic level (e.g., data codebook, statistical code, and generated results and figures). These will be made accessible to facilitate the interpretation and reproducibility of the scientific data.

RELATED TOOLS, SOFTWARE AND/OR CODE

Each Scientific Project will generate README files that contain documentation for all experiments to be conducted. These README files will include date, user, and detail of all activities conducted. Minimum detail included will be variable names and description, explanation of codes and classification systems, algorithms used to transform data, file format and software (including version) used.

All data and documentation will be organized into subfolders as follows:

- 'RawData': All raw data goes into this folder, with subfolders organized by date
- 'AnalyzedData': Data analysis files
- 'PaperDrafts': Draft of paper, including text, figures, outlines, reference library, etc.
- 'Documentation': Scanned copies of written research notes and other research notes
- 'Miscellaneous': Other information that relates to this project

In addition to consistent subfolder organization, the scientific projects aims will adopt a consistent naming structure.

Raw data files will be named as follows:

"YYYYMMDD_experiment_sample_ExpNum"
(ex: "20140224_UVVis_KMnO4_2.csv")

All files will be stored on the Johns Hopkins Secure Analytic Framework Environment (SAFE) desktop that is maintained (security and backup) by Johns Hopkins University IT. A staff member with expertise in data curation (see Budget Justification), working under the direction of Dr. Skolasky will ensure all data and documentation (including written research notes) are appropriately cataloged and stored in SAFE desktop on a weekly basis. In the event that data and documentation are not in SAFE desktop, Drs. Skolasky and McLaughlin will work with the co-investigators and study team to ensure compliance with this critical data management requirement.

The Johns. Hopkins SAFE Desktop provides access to Hopkins faculty and staff for analytic programs (e.g., Stata and R). Where possible, all documentation and code will be in the open-source R to allow redistribution to other investigators.

STANDARDS

We will work with the leaders of the scientific projects, the NIH program officer and staff, members of the HEAL Stewardship Group and the JHU Data Service to adhere to and/or to develop appropriate data standards for the storage and reporting of scientific data and associated metadata (e.g., data formats, dictionaries, identifiers, and definitions) as described in the principles and recommendations developed by the HEAL Data Ecosystem.

DATA PRESERVATION, ACCESS, AND ASSOCIATED TIMELINES

The name of the repository(ies) where scientific data and metadata arising from the project will be archived.

Johns Hopkins University (JHU) Data Archive

How the scientific data will be findable and identifiable, i.e., via a persistent unique identifier or other standard indexing tools.

We have developed the infrastructure (e.g., Research Electronic Data Capture (REDCap) and SAFE Desktop) to implement persistent unique identifiers and other standard indexing tools to ensure that scientific data will be findable and identifiable (ICTR, see Letter).

When the scientific data will be made available to other users (i.e., the larger research community, institutions, and/or the broader public) and for how long.

Data and research materials made available for public access will be shared through the JHU Data Archive, which uses an established repository platform (Dataverse) and is supported by preservation practices, with administrative help for preparing deposits provided by Johns Hopkins Data Services. Deposited data is given standard data citations and persistent identifiers (DOIs) and will be archived for a minimum of 5 years, with the possibility of renewal.

Data will be generated, quality assured, indexed, and stored to the specified timeline for this proposal

Under this Data Sharing and Management Plan, we will comply with Data Preservation and Sharing timelines. Shared scientific data will be made accessible as soon as possible, and no later than the time of an associated publication, or the end of the performance period, whichever comes first. Therefore, data will be deposited in the JHU Data Archive and made available at the time of publication or one year after the project, whichever is sooner.

ACCESS, DISTRIBUTION, OR REUSE CONSIDERATIONS

Describe any applicable factors affecting subsequent access, distribution, or reuse of scientific data related to:

- Informed consent (e.g., disease-specific limitations, particular communities' concerns).
    - The proposed study is considered human subject research.
        - Data from patients presenting to a primary care clinic serving rural communities with a diagnosis or problem list consistent with low back pain will be approached for screening, consent, and randomization following an IRB approved protocol. The participating health system will provide demographic and clinical information (e.g., name, contact information, age, gender, height, and diagnosis or problem list ICD-10 codes). The Johns Hopkins University School of Medicine IRB has review and approval authority over this activity.
- Privacy and confidentiality protections (i.e., de-identification, Certificates of Confidentiality, and other protective measures) consistent with applicable federal, Tribal, state, and local laws, regulations, and policies.
    - All data will be identified by a synthetic study identification number that is not linked to any personal health information.

OVERSIGHT OF DATA MANAGEMENT AND SHARING

Indicate how compliance with the Plan will be monitored and managed, frequency of oversight, and by whom (e.g., titles, roles).

Compliance with the Data Sharing and Management Plan will be monitored and managed by Dr. Richard Skolasky (MPI) working in coordination with Dr. McLaughlin (MPI) and Dr. Colantuoni (Co-I) with regular quarterly reporting to the internal committee comprised of scientific project leaders and regular reporting to the NIH program officer and staff and relevant HEAL consortium members.

These reports will include description of the type, location, and standards of experimental data (collected, analyzed, and stored), statistical and programming code, and metadata; the type, location, and standards of

physical collections (samples, images, and behavioral recordings); and progress of implementation of data sharing using the FAIR principles and NIH HEAL Initiative Public Access and Data Sharing Policy.

Monitoring and management will be discussed during regular consultation with the NIH Program Officer and staff and relevant HEAL consortium members.

NIH PRAGMATIC TRIALS COLLABORATORY
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I CAN DO Surgical ACP (Improving Completion, Accuracy, and Dissemination of Surgical Advanced Care Planning) Trial

DATA AND RESOURCE SHARING PLAN

Principal Investigators: Elizabeth Wick, MD; Genevieve Melton-Meaux, MD, PhD; Rebecca Sudore, MD

UCSF endorses and supports the rationale of the NIH that sharing data from all NIH-supported studies reinforces open scientific inquiry, encourages diversity of analysis and opinion, and promotes new research. Sharing data from all NIH-supported studies also allows the testing of new or alternative hypotheses and methods of analysis, supports studies on data collection methods and measurement, facilitates the education of new researchers, enables the exploration of topics not envisioned by the initial investigators, and permits the creation of new data sets when data from multiple sources are combined.

To do so, we will deposit data from the proposed project in the National Archive of Computerized Data on Aging (NACDA), maintained by ICPSR at the University of Michigan. To minimize disclosure risk, our research team will remove direct and indirect identifiers from data. To encourage data sharing, our publications from the proposed project will highlight the availability of data of the proposed project.

All 3 HCS have agreed to share the data from the proposed work as required by the UG3/UH3 mechanism, see letters of support from HCS leaders at UCSF (J. Adler, Chief Clinical Officer, UCSF Health), UCI (C. Lefteris, CEO UCI) and M Health Fairview (J. Hereford, CEO).

Pragmatic Trial Data Sharing
Access and Sharing: ICPSR will make the research data from this project available to the broader research community. These files may be accessed directly through the NACDA website. After agreeing to Terms of Use, users with an ICPSR MyData account and an authorized IP address from a member institution may download the data, and non-members may purchase the files.

Timeline: The research data from this project will be supplied to ICPSR by the end of the project so that any issues surrounding the usability of the data can be resolved. We will prepare the data appropriately, following NACDA best practices, to allow the NACDA/ICPSR staff to disseminate the data in a variety of media formats.

Intellectual Property Rights: The research team and their institutions hold the copyright for the research data they generate. By depositing with ICPSR, investigators do not transfer copyright but instead grant permission for ICPSR to re-disseminate the data and to transform the data as necessary to protect respondent confidentiality, improve usefulness, and facilitate preservation.

Ethics, Privacy, and Procedures: The proposed research will include data from approximately 6,000 surgical patients from UCSF, UCI and UMN, and will be managed jointly by Drs. Wick, Sudore and Melton. The final quantitative dataset will include demographic information, ACP outcomes and ACP engagement survey

results. We will redact the final quantitative dataset of identifiers prior to release for sharing including any identifying information.

Informed consent: For this project, informed consent statements will include language that allows for the survey data to be shared with the research community.

Disclosure risk management: The research team will remove any direct identifiers in the data before depositing with ICPSR. Once deposited, the data will undergo further procedures to protect participants' confidentiality. These include: 1) rigorous review to assess disclosure risk, 2) modifying data if necessary to protect confidentiality, 3) limiting access to datasets in which risk of disclosure remains high, and 4) consultation with data producers to manage disclosure risk. ICPSR will assign a qualified data manager certified in disclosure risk management to act as steward for the data while they are being processed. The data will be processed and managed in a secure non-networked environment using virtual desktop technology.

Format – Submission: The data and documentation will be submitted to ICPSR in recommended formats. Access: ICPSR will make the data files available in several widely used formats, including ASCII, tab-delimited (for use with Excel), SAS, SPSS, and Stata. Documentation will be provided as PDF.

Preservation: Data will be stored in accordance with prevailing standards and practice. Currently, ICPSR stores quantitative data as ASCII along with setup files for the statistical software packages, and documentation is preserved using XML and PDF/A.

Archiving and Preservation – ICPSR is a data archive with a nearly 50-year track record for preserving and making data available over several generational shifts in technology. ICPSR will accept responsibility for long-term preservation of the research data upon receipt of a signed deposit form. This responsibility includes a commitment to manage successive iterations of the data if new waves or versions are deposited. ICPSR will ensure that the research data are migrated to new formats, platforms, and storage media as required by good practice in the digital preservation community. Good practice for digital preservation requires that an organization address succession planning for digital assets. ICPSR has a commitment to designate a successor in the unlikely event that such a need arises. Storage and Backup – Research has shown that multiple locally and geographically distributed copies of digital files are required to keep information safe. Accordingly, ICPSR will place a master copy of each digital file (i.e., research data files, documentation, and other related files) in ICPSR's Archival Storage, with several copies stored with partner organizations at designated locations and synchronized with the master.

Code Sharing. Relevant resources, such as code used for data processing and analyses, will be made publicly available through GitHub (https://github.com), a code repository service also used by the NIH. GitHub is a web-based platform that host source codes, documentation, and project-related web content for research projects. Code documentation will include instructions on how to access data, the name of a contact person for questions, and all relevant references to publications. To ensure long-term accessibility, a copy of the GitHub code repository will be archived in Zenodo (https://zenodo.org/) at the time of publication. Zenodo is an open access repository that specializes in preserving software and issues DOIs for code. The code DOI will be included in each resulting publication.

Implementation Tool Sharing. In addition to the data collected as part of the trial, all the tools created will be freely available. This includes: patient facing materials (letters, telephone and text scripts, PREPARE materials) as well as EHR build information (randomization engine, outcome measurement data queries etc.)

NIH PRAGMATIC TRIALS COLLABORATORY
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Maternal OutcoMes (MOMs) Program: Testing Integrated Maternal Care Model Approaches to Reduce Disparities in Severe Maternal Morbidity

DATA MANAGEMENT AND SHARING (DMS) PLAN

Principal Investigator: Stephanie Fitzpatrick, PhD

Data Type

A. Types and amount of scientific data expected to be generated in the project: Summarize the types and estimated amount of scientific data expected to be generated in the project.

This study will collect clinical, psychosocial, and physical activity data from 674 individuals utilizing validated tools, electronic health records, and wearable device. Data collection tools, frequency of collection and type of data are listed below:

Type	Data Collection Tool	Time Frame/Amount	Brief Description
Objective Data: Severe Maternal Morbidity (SMM) Indicators	ICD-10 diagnosis codes of 21 indicators of SMM entered into the Northwell Health electronic health record during hospital admission	Labor and delivery; from labor and delivery to 1-month postpartum; from labor and delivery to 1-year postpartum	The Centers for Disease Control & Prevention defines SMM as having ≥ 1 ICD-10 diagnosis codes that correspond to the 21 SMM indicators. We will capture ICD-10 codes for each indicator per participant if they occur as well as a binary variable indicating 'yes or no' for SMM at the specified timepoints.
Objective Data: Preeclampsia	ICD-10 diagnosis codes associated with preeclampsia entered into the electronic health record	Will capture the incidence of preeclampsia throughout the prenatal period	ICD-10 codes associated with diagnosis of preeclampsia during the prenatal period will be extracted from the electronic health record and there will be a binary variable (preeclampsia 'yes or no') for each participant. We will also capture any history of preeclampsia during previous pregnancies as this will be used as one component to determine study eligibility.
Self-Report Data: Informational Support	PROMIS 10-item Informational Support measure	Administered at baseline, 1-month and 1-year postpartum	Validated questionnaire available in English and Spanish assessing patient's perceived support in terms of having someone that can provide facts and advice while helping to enhance their knowledge about a particular topic or issue. Data will be stored in REDCap, a secure online survey tool.

Self-report Data: Emotional Support	PROMIS 12-item Emotional Support measure	Administered at baseline, 1-month and 1-year postpartum	Validated questionnaire available in English and Spanish assessing patient's perceived support in terms of feeling like there is someone who cares and expresses concern and empathy. Data will be stored in REDCap, a secure online survey tool.
Self-Report Data: Tangible Support	8-item Tangible Support measure	Administered at baseline, 1-month and 1-year postpartum	Newly developed questionnaire assessing patient's perceived support in terms of having someone who can provide or help navigate a person to needed services and goods. Data will be stored in REDCap, a secure online survey tool.
Self-Report Data: International Physical Activity Questionnaire (IPAQ)	7-item International Physical Activity Questionnaire (IPAQ)	Administered at baseline, 1-month and 1-year postpartum	7-item validated questionnaire to measure frequency and duration of moderate and vigorous physical activity, walking, and sitting. Data will be stored in REDCap, a secure online survey tool.
Self-Report Data: Barriers to Exercise Scale	14-item Barriers to Exercise Scale	Administered at baseline, 1-month and 1-year postpartum	14-item validated questionnaire to measure barriers to exercise. Data will be stored in REDCap, a secure online survey tool.
Self-Report Data: Behavioral Regulation in Exercise Questionnaire	24-item Behavioral Regulation in Exercise Questionnaire	Administered at baseline, 1-month and 1-year postpartum	24-item validated questionnaire to measure participant's motivation to exercise. Data will be stored in REDCap, a secure online survey tool.
Objective Data: Wearable physical activity monitor	Fitbit	Continuously from study enrollment to 1-year postpartum	Participants will be asked to wear a Fitbit daily from the time of study enrollment to 1-year postpartum to capture (at a minimum) frequency, intensity, and minutes of physical activity bouts.
Obstetrics Comorbidities	Obstetrics Comorbidity Index (OB-CMI)	Baseline One measurement	This validated, weighted index takes into account the number and severity of possible comorbid conditions/ maternal health factors associated with increased risk for severe maternal morbidity. Data will be captured from the electronic health record and stored in REDCap as it will be used as study inclusion criteria.
Sociodemographics	Extracted from electronic health record and confirmed during study enrollment	Baseline One measurement	Patient race, ethnicity, age, sex, gender, and preferred language will be extracted from the electronic health record and confirmed during the study enrollment call. Neighborhood-level household income and educational attainment will be determined using patient addresses and publicly available Census data. Data will be stored in REDCap.

B. Scientific data that will be preserved and shared, and the rationale for doing so: Describe which scientific data from the project will be preserved and shared and provide the rationale for this decision.

Participant data related to the primary and secondary outcomes will be shared with scientists on the Open Science Framework (OSF) repository. This will include the 21 severe maternal morbidity indicators, preeclampsia diagnosis, and responses to the perceived social support domain measures. We will also include data relating to exploratory analyses (physical activity questionnaires; Fitbit data summarizing frequency, intensity, and minutes of physical activity bouts), including data for variables which may moderate the primary analyses (e.g., sociodemographics, comorbidity). The goal of all shared data will be to facilitate replication of all primary and secondary, and exploratory study analyses as well as to allow for additional analyses with available data. Data will be redacted to strip all individual identifiers, and effective strategies should be adopted to minimize risk of disclosing a participant's identity. Whenever possible, raw participant-level data will be shared along with documentation of how variables were cleaned, coded, or summarized. In cases where participant-level data could be used to identify individuals, summary data will be presented rather than raw data. Information about how summary data was generated will be provided in the data dictionary.

C. Metadata, other relevant data, and associated documentation: Briefly list the metadata, other relevant data, and any associated documentation (e.g., study protocols and data collection instruments) that will be made accessible to facilitate interpretation of the scientific data.

A copy of the study protocol, informed consent form, manual of operations and assessment tools will also be posted on Open Science to facilitate interpretation of the scientific data. This will include descriptions of the variables measured, interpretations of the variables, information about variable coding, and information regarding standardized measures. In addition, data analysis code will be posted from the statistical software utilized in the primary analyses (SAS or R) to allow for replication of study analyses. All analysis code will be annotated and/or presented with comments to allow for easier replication of study findings.

Related Tools, Software and/or Code

State whether specialized tools, software, and/or code are needed to access or manipulate shared scientific data, and if so, provide the name(s) of the needed tool(s) and software and specify how they can be accessed.

No special tools will be needed to access shared scientific data from this project. Raw and summarized data will be provided in readily accessible formats (e.g. ".csv") which can be utilized by most data management or analysis software programs. It is possible that particular data visualizations presented in dissemination activities (e.g. publications, presentations, posters, etc.) may be linked to specific software. For example, a figure visualizing an outcome may be generated using a particular package in the statistical software R. In these cases, descriptions of how figures were generated will be included and citations will be made to the software/methods used.

Standards

State what common data standards will be applied to the scientific data and associated metadata to enable interoperability of datasets and resources and provide the name(s) of the data standards that will be applied and describe how these data standards will be applied to the scientific data generated by the research proposed in this project. If applicable, indicate that no consensus standards exist.

All data will be coded and without any personal health information, individual identifying information, and any data elements which may include HIPAA identifiers. This may lead to displaying summary data (e.g., a categorical age variable rather than a continuous age). In cases where data is presented in a summarized format, the coding of these variables will be clearly defined in the associated data dictionary. For previously existing measures (e.g., severe maternal morbidity, PROMIS social support questionnaires), data will be

stored and scaled scores will be developed using traditional coding methods previously applied in scientific literature and/or clinical practice. A data dictionary will be provided clearly identifying how individual variables are coded (e.g., how response options correspond to numeric scores) and evaluated (e.g., indicating that higher scores correspond to higher levels of the measured construct). The data dictionary will provide the necessary context for interpretation of the raw and summary data. In addition to the data dictionary, all publications will include clear descriptions and citations for each measure used.

Data Preservation, Access, and Associated Timelines

A. Repository where scientific data and metadata will be archived: Provide the name of the repository(ies) where scientific data and metadata arising from the project will be archived; see Selecting a Data Repository).

Study data and metadata will be stored on the Open Science Framework (OSF) platform and available in advance of the first publication of study outcomes or the end of the award period, whichever comes first. De-identified data will be stored on OSF indefinitely to allow for continued access.

B. How scientific data will be findable and identifiable: Describe how the scientific data will be findable and identifiable, i.e., via a persistent unique identifier or other standard indexing tools.

The URLs for all projects, components, and files on OSF are GUIDs. Any inclusion of URLs in published manuscripts will enable readers to find the particular files referenced. Additionally, a citation is automatically generated for each project and component on OSF. This citation can be included in the reference sections of articles citing the files, so that all contributors who shared data, code, and materials are properly credited when those files are reused. All dissemination activities (including publications, presentations, posters, etc.) will include references and the URL address for the OSF platform where data is stored to ensure easy access.

C. When and how long the scientific data will be made available: Describe when the scientific data will be made available to other users (i.e., no later than time of an associated publication or end of the performance period, whichever comes first) and for how long data will be available.

As stated above, study data and metadata will be stored on the Open Science Framework (OSF) platform and available in advance of the first publication of study outcomes or the end of the award period, whichever comes first. De-identified data will be stored on OSF indefinitely to allow for continued access.

Access, Distribution, or Reuse Considerations

A. Factors affecting subsequent access, distribution, or reuse of scientific data: NIH expects that in drafting Plans, researchers maximize the appropriate sharing of scientific data. Describe and justify any applicable factors or data use limitations affecting subsequent access, distribution, or reuse of scientific data related to informed consent, privacy and confidentiality protections, and any other considerations that may limit the extent of data sharing. See Frequently Asked Questions for examples of justifiable reasons for limiting sharing of data.

To comply with de-identification guidelines, some variables may be omitted or presented in summary format in the data posted on Open Science Framework. The goal for removing this information is to prevent disclosure of personal health information (PHI) or identifiable information. For individuals who wish to have access to the full dataset (including information which may identify individual participants), a request for data can be made to the study principal investigator (in this case Dr. Fitzpatrick) and to the regulatory team for the Institute of Health System Science (IHSS) at Northwell Health. Data requests will be reviewed by the regulatory team and access to full data will be granted following Northwell Health Institutional Review Board (IRB) approval, as applicable,

and completion of a data use and sharing agreement with Northwell Health. Details about the process for requesting additional data and contact information for both the study PI and the IHSS regulatory team will be clearly detailed in the OSF posting. This will include contact information for the PI and members of the regulatory team as well as directions for making data requests.

B. Whether access to scientific data will be controlled: State whether access to the scientific data will be controlled (i.e., made available by a data repository only after approval).

De-identified study data will be made freely available to all interested individuals via the posting to OSF. Access to data which may contain PHI or individually identifiable information will require a formal data request and approval from the Northwell Health IRB as detailed above.

C. Protections for privacy, rights, and confidentiality of human research participants: If generating scientific data derived from humans, describe how the privacy, rights, and confidentiality of human research participants will be protected (e.g., through de- identification, Certificates of Confidentiality, and other protective measures).

Data collected in this study will only be collected from participants who meet initial study eligibility criteria following screening, and who participate fully in the informed consent process. This includes listening and asking questions during the reading of the Northwell IRB consent document by a research assistant over the phone, containing all of the elements of informed consent required by 45 CFR 46.116 and elements of authorization required by the HIPAA Privacy Rule, and the provision of verbal consent. Participants will be able to request that a copy of the consent document be emailed or mailed to them for future reference. The consent document will notify participants that data collected and generated from this funded project will be made available for future research so that individuals are fully informed of this data sharing practice. Additionally, direct communication with research personnel via encrypted email, text message, phone or video call is available. Research assistants will be available to answer participants' questions and communicate in the participant's preferred language (English or Spanish).

OSF provides the technical facility for effective ethical management and privacy of storing human data so that data collected during this study that can identify participants will be kept confidential. OSF maintains a Data Retention & Destruction Policy so data is protected from unauthorized access, information is maintained only for the required time to reduce risk, and an audit trail is recorded and maintained. OSF database backups are maintained in encrypted snapshots for 60 days. Logs are retained indefinitely. File backups are hosted in Google Cloud Coldline storage indefinitely. Upon deletion by users, files are retained for 30 days before being removed. Researchers entering data on OSF can set sensitive data to private. This will prevent data from being shared outside of approved collaborators. Projects can also be set to "request access" control to enable access requests with review for appropriate credentials. This provides an additional layer of security for posting data to OSF which reduces the likelihood of accidental disclosure of data.

Prior to depositing into OSF, the risk of loss of confidentiality will be minimized by securely storing research data, including PHI, in a Northwell-approved, password-protected, HIPAA complaint database. No paper documents with personal identifiers will be kept. The Principal Investigator (PI) will be responsible for ensuring that the confidentiality of the data is maintained at all times. All data will be obtained specifically for research purposes. Participant data will be assigned a code number and separated from the participants' name or any other information that could identify him/her. The research file that links identifiable information to the study code will be kept in an encrypted data file and only the PI and IRB-approved study staff will have access to the file or any other electronic research file. All these activities will be conducted with rigor, reproducibility and Open Science best practices.

Oversight of Data Management and Sharing

Describe how compliance with this Plan will be monitored and managed, frequency of oversight, and by whom at your institution (e.g., titles, roles)

Compliance with this plan will be monitored by the Principal Investigator over the course of the funding period during regular reporting intervals (e.g., at the time of annual Research Performance Progress Reports (RPPRs)).

Reaching Rural Veterans: Applying Mind-Body Skills for Pain Using a Whole Health Telehealth Intervention (RAMP)

RESOURCE AND DATA SHARING PLAN

Principal Investigators: Diana Burgess, PhD; Roni L. Evans, DC, MS, PhD; Katherine E. Hadlandsmyth, PhD

The resource sharing plan or data management and sharing plan will comply with the HEAL Initiative Public Access and Data Sharing Policy, the HEAL PRISM (Pragmatic and Implementation Studies to Improve the management of Pain and Reduce Opioid Prescribing) Program's Data Sharing Policy; and will also comply with local institutional policies and local, state and federal laws and regulations including the Health Insurance Portability and Accountability Act (HIPAA) Privacy and Security Rules.

This resource sharing plan refers to both Phase 1 (UG3) and Phase II (UH3) of the proposed project. It is consistent with the FAIR (Findable, Accessible, Interoperable, and Reusable) data principles in accordance with the NIH, HEAL Initiative, and PRISM Program,

Release of Publications and Data
Publications from this research will be made available to the public through the National Library of Medicine PubMed Central website within one year after the date of publication. Final data sets underlying all publications resulting from the proposed research will be shared outside VA. The data sets will include research involving human subjects. Where practicable, Limited Datasets (LDSs) will be created and shared pursuant to a Data Use Agreement (DUA) appropriately limiting use of the dataset and prohibiting the recipient from identifying or re- identifying (or taking steps to identify or re-identify) any individual whose data are included in the dataset. Final deidentified, anonymized datasets in machine-readable format may be created and shared via PubMed Central (and similar) sites with care taken to ensure that the individuals cannot be reidentified using other publicly available information.

Data Type
Data generated by this research is derived from UG3 (N=40) and UH3 (N=500) participants and associated activities. Data will include participant-reported outcome measures including recommended common data elements (CDEs) from the HEAL initiatives core pain domains in addition to baseline demographic, occupational, health characteristics including PhenX ToolKit social determinants of health measures (see **Research Strategy** for all measures). VA PHI and VA sensitive data will be securely stored on a VA Research network drive behind the VA firewall or secured file cabinet. No PHI or VA sensitive data will be shared, unless approved by VA Privacy Officers. Only authorized research personnel as approved by the ACOS in agreement with the PI, will have access to individually identifiable data.

The research project team and PRISM/Collaboratory Program Coordinating Center will work together in order to offer deidentified or limited data sets that will be available to the public. Case-report forms

will be submitted to the HEAL Clinical Data Elements (CDE) Program to ensure standardized variable names, responses, coding, and other information. We understand that formatting the case-report forms will be done in a such a standardized way that is compliant with accessibility standards under Section 508 of the Rehabilitation Act of 1973, which "requires Federal agencies to make their electronic and information technology accessible to people with disabilities".

The study team will obtain licenses for all copyrighted questionnaires prior to initiating data collection. Licenses will be shared with the HEAL CDE team and the program officer prior to use of copyrighted materials. Study protocols, data collection instruments, and data dictionaries will be made available to facilitate interpretation of publicly available data sets.

Related Tools, Software and/or Code

This project does not intend to develop any standalone software packages so there are no timelines for making full software packages available to be shared outside of the research team.

However, this project's research team is expert in the use and development of code for extraction of data from VA electronic data systems. Our team intends to be a very active participant on the PRISM/Collaboratory Program Coordinating Center's Work Groups. The Center for Care Delivery and Outcomes Research (CCDOR) has a data team, led by Co- Investigator Dr. Brent Taylor, which creates customized research applications based on the needs of each research project. These applications allow project staff to recruit, enroll, randomize participants to the study, and complete follow-up assessments of study outcomes. These customized applications operate behind the VA firewall in order to protect participant data and they are developed in such a way that they cannot be easily transferred to other research settings. So, while the code for these applications would not be terribly useful for other research groups because it is highly customized for CCDOR systems, the general concepts underlying these applications is able to be shared. Also, in working with other members of the PRISM/Collaboratory Program, we might be able to come up with sections of code that can help improve the workflow for other research teams.

The program assets created by the study team and used during this research project will potentially be made available for other platforms to incorporate. If shown to be successful, the goal would be for the key components of this content to be widely disseminated. This project will work closely with the Coordinating Center to disseminate these research findings and content.

Aside from the software code that is developed by CCDOR programmers for the day-to-day work of running the research study, this project will also be contracting with Qualtrics FedRAMP, a survey and communications vendor. Initial screening and survey data will be securely stored on Qualtrics FedRAMP VA cloud servers that are approved and fully compliant to house VA research data.

Standards

The research project team will work closely with the PRISM/Collaboratory Program Coordinating Center to provide deidentified or limited data sets that will be available to the public. The MPIs (Multiple Principal Investigators) (or designee) will ensure all data will be kept in consistent standardized data formats throughout the duration of the study. Data will be collected, processed, archived and shared in accordance with guidelines from the HEAL Data Ecosystem. We anticipate that the PRISM/Collaboratory Program Coordinating Center will develop infrastructure to allow independent research groups to request access to view relevant data from this project in order to evaluate the extent that data support conclusions made by authors in published studies as well as view supplemental details that might not be included in publications.

Data Preservation, Access and Associated Timelines
Data generated by the project will be submitted to study-appropriate repositories in consultation with the HEAL Data Stewardship Group to ensure the data is accessible via the HEAL Initiative Data Ecosystem and PRISM Program.

Access, Distribution or Reuse Considerations
Informed consent. Potential risks associated with data sharing include a breach of confidentiality. This will be minimized as all identifiable data will be kept within the VA firewall and even within the VA firewall analytical datasets will be assigned a unique study specific identifier such that participant identifiers (e.g., name, SSN, addresses, medical numbers, etc.) can be separated from study variables. Prior to the start of the study, the PIs and local IRB will assess informed consent materials to determine whether the Underlying Primary Data may be shared as contemplated in this Policy and make adjustments as needed to conform to this data sharing policy. To the extent possible, broad data sharing, data access, and reuse requirements will be integrated into informed consent and/or information sheet forms, as guided by HEAL.

Privacy and confidentiality protections. Scientific data that is shared will be aggregated when possible and any individual level data will be deidentified (e.g., no participant identifying information). VA Privacy Officers will review and approve the release of any individual data to insure the protection of VA patient data. The MPIs (or designee) will ensure all data will be kept in consistent standardized data formats throughout the duration of the study. Data will be collected, processed, archived and shared in accordance with VA guidelines.

Oversight of Data Management and Sharing
Oversight and compliance with the proposed resource sharing plan will be monitored on a routine basis (monthly to quarterly depending on need and phase of the project) by the PIs and Data & Technology Team (see **Section 3.5 Structure of the Study Team**).

NIH COLLABORATORY POLICIES AND GUIDELINES

NIH Pragmatic Trials Collaboratory Data Sharing Policy

Introduction

The Collaboratory Steering Committee recognizes that data sharing promotes many goals of the NIH research endeavor. It is particularly important for unique data that cannot be readily replicated. Data sharing allows scientists to expedite the translation of research results into knowledge, products, and procedures to improve human health.

There are many reasons to share data from these NIH-supported studies. Sharing data reinforces open scientific inquiry, encourages diversity of analysis and opinion, promotes new research, makes possible the testing of new or alternative hypotheses and methods of analysis, supports studies on data collection methods and measurement, facilitates the education of new researchers, enables the exploration of topics not envisioned by the initial investigators, and permits the creation of new datasets when data from multiple sources are combined.

The Collaboratory Steering Committee agrees that data should be made as widely and freely available as possible while safeguarding the privacy of participants, and protecting confidential and proprietary data, and therefore adopts the following policy regarding data sharing:

Policy

1. Collaboratory investigators will each share, at a minimum, a final research data set upon which the accepted primary pragmatic trial publication is based.
2. The Collaboratory Steering Committee recognizes that sharing data derived from clinical care in studies performed in partnership with health care systems may, under some situations, require precautions in addition to those regarding patient confidentiality, to protect specific interests of collaborating health care systems, facilities or providers. Precautions such as allowing data sharing in more supervised or restricted settings, such as access to researchers who agree to limited pre-approved research goals, may be appropriate to address these needs in implementing this data sharing policy.
3. Consistent with NIH policy and guidance, Collaboratory investigators will choose the least restrictive method for sharing of research data that provides appropriate protection for participant privacy, health system privacy, and scientific integrity.
4. Collaboratory investigators will work with NIH to implement this data sharing policy, to ensure the appropriate administrative processes and technical infra-structure are in place to support timely data sharing for the Collaboratory.

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NIH Pragmatic Trials Collaboratory Data Sharing Considerations

Objectives

Sharing research data collected in Collaboratory pragmatic trials is essential to several core objectives of the Collaboratory program, including:

- Maximizing the public health impact of the significant NIH investment in these large projects;
- Accelerating the pace of learning throughout the US healthcare system; and
- Increasing participation in research and learning by a wide range of stakeholders, including healthcare systems, healthcare providers, and patients/consumers

The ethical responsibility to share data generated by publicly funded research must be balanced against the need to protect patient privacy and scientific integrity.

Because Collaboratory trials typically rely on data collected through normal health care delivery, sharing data from those trials will be guided by some considerations not typically encountered in more traditional clinical trials. For example, individual participant consent may be waived in accordance with the federal regulations for the Protection of Human Subjects (45 CFR part 46) in some NIH Collaboratory Pragmatic trials that rely on data extracted from health systems' electronic medical records or administrative data. Special considerations in developing data sharing for pragmatic trials involving health system data are discussed in the accompanying guidance document, "Considerations Regarding Sharing of Health Systems Data."

Existing Regulatory Requirements

All NIH Collaboratory Pragmatic Trials are expected to adhere to existing NIH Data Sharing Policy and Implementation Guidance (http://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm). Key points in that policy and guidance include:

- The privacy of participants should be safeguarded.
- Data should be made as widely and freely available as possible.
- Data should be shared no later than the acceptance for publication of the main study findings.
- Initial investigators may benefit from first and continuing use of data, but not from prolonged exclusive use.

NIH defines the data to be shared as the "recorded factual material commonly accepted in the scientific community as necessary to document, support, and validate research findings. This does not mean summary statistics or tables; rather, it means the data on which summary

statistics and tables are based. For most studies, final research data will be a computerized dataset. For example, the final research data for a clinical study would include the computerized dataset upon which the accepted publication was based, not the underlying pathology reports and other clinical source documents. For some but not all scientific areas, the final dataset might include both raw data and derived variables, which would be described in the documentation associated with the dataset."[1]

Special Considerations Regarding Use of Health System Data

The NIH policy recognizes that data may need to be modified prior to sharing to protect participant's privacy. Data may need to be redacted to strip identifiers, and data use agreements requiring confidentiality may be required. It may be appropriate under certain circumstances to limit access to sensitive data under stricter controls such as those possible through a data enclave.

Given that the NIH Collaboratory trials rely on data extracted from health systems' electronic medical records or administrative data, it is important to distinguish between research data and the original health system data from which research data were extracted. Each Collaboratory trial is allowed to create and/or use specific health information through either an explicit informed consent process and/or a waiver of consent granted by one or more supervising Institutional Review Boards. While Collaboratory trial personnel may have access to a wide range of original health system data (Electronic Health Records, insurance claims, etc.), trials are only allowed to use and store data elements specifically authorized for research use - either by participant consent or by formal waiver of consent by the responsible Institutional Review Board (s).

Investigators are not expected to share or give access to original health system data in electronic medical records or other administrative data systems. Rather, they are expected to give access only to the research data on which their analyses are based and conclusions drawn. For example: A Collaboratory trial may be authorized by participant consent or waiver of consent to examine Electronic Health Records and insurance claims data to assess adherence to a specific class of medications for each trial participant. Computing specific measures of medication adherence may require trial personnel to access all available information regarding medications ordered and/or prescriptions filled. In accord with the consent limits, however, investigators would only retain and analyze specified data elements. In most cases, the detailed original data regarding all medications ordered and/or prescriptions filled would not be retained by investigators and would not be subject to any expectations or requirements for data sharing.

It is recognized that sharing data derived from clinical care in studies performed in partnership with health care systems may, under some situations, require additional precautions to protect specific interests of collaborating health care systems, facilities or providers. Precautions such as allowing data sharing through a restricted data enclave in

[1] NIH Data Sharing Policy and Implementation Guidance (http://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm).

which access is limited to researchers who agree to limited pre-approved research goals may be appropriate to address these needs in developing data sharing practices.

Methods and Tools for Data Sharing

A range of technical options are available for sharing data with external users:

- **Unsupervised Data Archive** – Data that cannot be linked to individuals are made available for unrestricted public use. Potential users are not asked to propose specific questions or analytic plans, and users are not expected to account for any use or re-disclosure.
- **Unsupervised Public Data Enclave** – Data are not shared with external users. Instead, users are allowed to submit queries – typically through an online portal. "Unsupervised" means that queries are executed automatically, without prior review or requirement for prior approval. "Public" implies that any member of the public could submit queries. Risk of identifying individual data or other misuse can be managed by limiting the identifiability of the dataset to which queries are submitted, limiting the complexity of queries users are allowed to submit, or by limiting the level of detail of results that are returned.
- **Unsupervised Private Data Enclave** – This arrangement would be identical to an unsupervised public enclave, except that access would be limited to specific registered or pre-qualified users. "Unsupervised" means that individual queries are executed automatically, without prior review or any requirement for prior approval.
- **Supervised Data Archive** – Data that cannot be linked to individuals are made available to approved users for specific pre-approved purposes. Users are typically expected to propose specific questions or analyses, and use of data is limited to specific approved uses. Written documentation of requests and conditions for release are common. Disclosure to third parties is typically restricted or forbidden unless required by law. These limits or restrictions can be documented in contracts or other agreements.
- **Supervised Data Enclave** – Data are not made available to external users. Instead, users submit queries to data (typically through an online portal). "Supervised" means that all queries are reviewed and approved before execution and return of results.

These different methods allow different levels of and mechanisms for, privacy protection. At one extreme, an unsupervised data archive allows no control or protection once data are shared with users, so protection depends completely on the dataset contents. At the other extreme, a supervised data enclave allows complete control and protection over user qualifications, query logic, query topic, and return of results. In some cases, these additional levels of protection will allow investigators to share data that could not be appropriately shared through less controlled or supervised mechanisms.

Expectations for Collaboratory Trials

At minimum, Collaboratory investigators must prepare and share a final research data set upon which the accepted primary pragmatic trial publication is based. Data sets will be structured to maximize future scientific value while protecting patient and health system privacy.

- Data should not include any of the 18 HIPAA-specified direct identifiers
- Investigators should have reason to expect that the data cannot be used to identify a subject, or that the risk of re-identification is "very small."

The Department Health and Human Services guidance regarding HIPAA-compliant data sharing (http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/De-identification/guidance.html#idrisk) describes specific methods for reducing risk of re-identification, including generalization (or aggregation) of specific variables and suppression of individual values or observations.

Collaboratory trials may also choose to make more detailed data available through one of the more restricted options described above. Sharing additional data through one of these more restricted mechanisms is appropriate when sharing such data would have scientific or public health value but also increase risk of re-identification or other misuse.

In addition to measures necessary to prevent re-identification of individual study participants, additional measures may be necessary to prevent re-identification of providers or facilities. For example: A hypothetical trial might include patients from five clinics serving patient populations with markedly different racial and ethnic composition. A dataset including "blinded" clinic identifiers as well as participant race and ethnicity might allow users to re-identify participating clinics. An investigator sharing these data using one of the unsupervised approaches described above could prevent such re-identification by creating distinct datasets – one including clinic identifier and one including participant race and ethnicity. An investigator sharing these data using one of the supervised approaches described above could limit queries or analyses to those that would not re-identify participating clinics.

Consistent with NIH policy and guidance, investigators should choose the least restrictive method that provides appropriate protection for participant privacy, health system privacy, and scientific integrity. In addition, more supervised or restricted options will typically require a higher level of resources (technical infrastructure, investigator time, other staff time) to support.

Questions for Steering Committee Discussion

1. Do we accept the policy that all Collaboratory trials are expected to develop and share an appropriately de-identified analytic dataset?
2. If we accept that policy, is a 6-month timeframe after publication an appropriate deadline for sharing of that dataset?
3. Where will the Collaboratory data sets be archived?
4. If Collaboratory trials are able to share more detailed data through some more limited process (e.g. supervised data archive, supervised data enclave), will the NIH Collaboratory Program provide the ongoing resources to govern and manage that process?

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Assessing Fitness-for-Use of Clinical Data for PCTs

Background

The credibility and reproducibility of pragmatic clinical research depends on the investigator's demonstration that the data are of sufficient quality to support the research conclusions. This document highlights recommendations for assessing the fitness-for-use of data generated from routine patient care for use in pragmatic clinical trials (PCTs). For more information, read the full chapter in the Living Textbook: Assessing Fitness for Use of Real-World Data.

Before using an electronic health record (EHR) dataset for a given research project, one should determine whether it is fit-for-purpose by determining if the data are **relevant** and **reliable**. Relevance includes the availability of key data elements (exposures, outcomes, covariates) and sufficient number of representative patients for the study. Reliability includes data accuracy, completeness, provenance, and traceability (FDA 2021).

More specifically, a real-world data source is said to be **relevant** if:

- The data apply to the question at hand
  - For example, the data contain sufficient detail to capture the use or exposure of the product or device and/or the outcome of interest
- The data are amenable to sound clinical and statistical analysis
  - For example, the data can be used to answer the specified question using the proposed statistical plan
- The data and evidence the source provides are interpretable using informed clinical and statistical judgement.
  - For example, the use of a device or product in a real-world population is representative of what is captured in the data source, is generalizable to the relevant population under study, etc. (FDA 2018).

Data are considered **reliable** if:

- Data are captured in a standardized and rigorous manner
- Data are accurate and complete, data provenance is known, and data are traceable
- Efforts of data curation, transformation, accrual, etc. are known (i.e., process from transforming raw data to analytic dataset)

EHR data typically go through several phases when used to support a PCT—from source system, to clinical data repository to data warehouse to study-specific dataset. The quality or fitness of a dataset may be evaluated at various points along this process, with different processes for quality assurance or quality control (FDA 2021). Assessment of data quality is on ongoing process, and conformance, completeness, and plausibility should be assessed throughout the trial.

Data Quality Checks

Example data checks to evaluate conformance, completeness, and plausibility are provided in the table below.

Table 1. Categories of Data Quality Checks and Examples From Distributed Research Networks

Category	Subcategory	Description	Data Check Example
Conformance	Value	Determines whether the data conform to the formats of the data model used to store them	Sex values are F, M, or U; age is in specified range
	Relational	Determines whether the data agree with the constraints imposed by the database used to store them (e.g., primary or foreign key relationships)	All patient medical record fields are present in each table that requires them
	Calculation	Evaluates whether variables derived computationally yield valid results	Enrollment periods do not overlap; computed BMI is correct
Completeness		Examines whether expected values are present (single time point or longitudinally)	Gender is not null
Plausibility	Uniqueness	Determines whether multiple values exist when only one value is expected	Patient does not have multiple inpatient admissions to the same facility on the same day
	Atemporal	Measures whether data agree with expected values	Most of the records are not in the lowest or highest categories of age, height, weight, diastolic blood pressure, etc.
	Temporal	Examines whether variables change as expected over a specified time period	Events are not before date of birth or after date of death

For more details see: A Harmonized Data Quality Assessment Terminology and Framework for the Secondary Use of Electronic Health Record Data and the FDA Guidance for Industry, Real-World Data: Assessing Electronic Health Records and Medical Claims Data To Support Regulatory Decision-Making for Drug and Biological Products

Data Quality Assessment Recommendations for PCTs

1 – Key data quality dimensions

We recommend that conformance, completeness, and plausibility be formally assessed for data elements used in subject identification, outcome measures, and important covariates.

2 – Reporting data quality assessment with research results

Results of data quality assessments should be reported with research results. Data quality assessments are the only way to demonstrate that data quality is sufficient to support the research conclusions, and as such should be accessible to consumers of research.

Food and Drug Administration. 2018. Framework for FDA's Real World Evidence Program. https://www.fda.gov/media/120060/download. Accessed July 12, 2022.
Food and Drug Administration. 2021. Real-World Data: Assessing Electronic Health Records and Medical Claims Data To Support Regulatory Decision-Making for Drug and Biological Products. https://www.fda.gov/media/152503/download. Accessed July 12, 2022.

The NIH Pragmatic Trials Collaboratory is supported by the National Institutes of Health (NIH) through cooperative agreement U24AT009676 from the Office of Strategic Coordination within the Office of the NIH Director. It is also supported by the NIH through the NIH HEAL Initiative under award number U24AT010961. The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH or its HEAL Initiative. To learn more about the program, visit rethinkingclinicaltrials.org.

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Publications, Presentations, and Products Policy

CONTENTS

I. Purpose 2
II. Definitions 2
III. Publications, Presentations, and Products Committee 4
IV. Demonstration Project Publications and Presentations 5
V. Core Working Group Publications and Presentations 6
VI. Core Working Group Guidance Documents 8
VII. Core Working Group Tools, Best Practice Documents, and Other Resources 10
VIII. Short Communications by the Coordinating Center 11
IX. Acknowledgment of NIH Pragmatic Trials Collaboratory Support 11

I. Purpose

The National Institutes of Health (NIH) Pragmatic Trials Collaboratory is supported by an NIH-funded cooperative agreement. A principal goal of the NIH Collaboratory is to produce generalizable knowledge by publishing high-quality, timely research findings and perspectives in the peer-reviewed literature; delivering presentations of NIH Collaboratory scholarship in public forums; and sharing guidance, tools, best practices, and other resources for healthcare systems research.

It is recognized that NIH Pragmatic Trials Collaboratory investigators will publish manuscripts, submit abstracts, and deliver presentations that directly reflect NIH Collaboratory activities. Investigators will also publish manuscripts, submit abstracts, and deliver presentations that either mention NIH Collaboratory activities or address topics that are related to NIH Collaboratory activities but are funded from other sources.

The NIH Pragmatic Trials Collaboratory includes the individual Demonstration Projects, the Core Working Groups, and ad hoc working groups, all of which may develop publications, presentations, and other products. Manuscripts, abstracts, presentations, and other products derived from NIH Collaboratory–supported activities will be designated as NIH Collaboratory products.

II. Definitions

A. Demonstration Project Publications and Presentations

Demonstration Project publications and presentations are manuscripts, abstracts, and presentations that deal directly with knowledge derived from a Demonstration Project. For example, a manuscript, abstract, or presentation that reports methods or results of a Demonstration Project is a Demonstration Project publication or presentation. Review and approval of Demonstration Project publications and presentations will follow the procedures described in Section IV of this policy.

B. Core Working Group Publications and Presentations

Core Working Group publications and presentations are manuscripts, abstracts, and presentations produced by a Core Working Group as part of the Core's efforts to create generalizable knowledge. For example, a manuscript, abstract, or presentation that reports a comparison of methods for validating phenotypes across Demonstration Projects undertaken by members of a Core is a Core Working Group publication or presentation. Review and approval of Core Working Group

publications and presentations will follow the procedures described in Section V of this policy.

C. Guidance Documents

Guidance documents are official statements by the NIH Pragmatic Trials Collaboratory meant to describe procedures or principles for the conduct of healthcare systems research. These documents are intended to have an enduring quality and to represent a synthesis of considerable evidence. Guidance documents may be produced by 1 or more Core Working Groups or by an ad hoc working group. Guidance documents are published on the NIH Collaboratory website. Review and approval of guidance documents will follow the procedures described in Section VI of this policy.

D. Tools, Best Practice Documents, and Other Resources

Tools, best practice documents, and other resources are products that represent a consensus within 1 or more Core Working Groups about approaches to healthcare systems research. Examples include, but are not limited to, checklists, tips and frequently asked questions, executive summaries, and other information resources. Tools, best practice documents, and other resources are intended to evolve and may be subject to frequent revision as lessons emerge from the Demonstration Projects and Core Working Groups. Tools, best practice documents, and other resources are published on the NIH Pragmatic Trials Collaboratory website. Review and approval of tools, best practice documents, and other resources will follow the procedures described in Section VII of this policy.

E. Short Communications

Short communications are products hosted on the NIH Pragmatic Trials Collaboratory website or social media accounts—such as news articles, video and audio recordings, and tweets—about NIH Collaboratory activities and other topics relevant to healthcare systems research. Short communications are produced by the Coordinating Center communications team in consultation with the Coordinating Center leadership. Review and approval of short communications will follow the procedures described in Section VIII of this policy.

III. Publications, Presentations, and Products Committee

A. Members and Decision Making

The Publications, Presentations, and Products Committee ("Publications Committee") consists of Coordinating Center investigators, Demonstration Project representatives, and the NIH project officer and project scientist, as well as nonvoting Coordinating Center staff who serve as committee staff. The Coordinating Center leadership appoints the chair of the committee. Decisions of the committee will be made by majority vote, although consensus will be sought in all cases.

B. Responsibilities

1. The Publications Committee oversees all NIH Pragmatic Trials Collaboratory–supported publication and presentation activities, with final adjudication of decisions made by the Steering Committee as needed. Oversight includes the following specific activities:

    a. The Publications Committee reviews and approves (1) Core Working Group manuscripts before they are submitted and (2) guidance documents before they are published to ensure that descriptions of NIH Pragmatic Trials Collaboratory activities are accurate and to share comments and suggestions. Committee staff review these documents to ensure the use of required acknowledgment and disclaimer language.

    b. Committee staff reviews Demonstration Project manuscripts before they are submitted to ensure the use of required acknowledgment language and to check for mentions of other Demonstration Projects. Committee staff also reviews tools, best practice documents, and other resources before they are published on the NIH Pragmatic Trials Collaboratory website to ensure the use of required acknowledgment and disclaimer language and to check for mentions of Demonstration Projects.

2. The Publications Committee also monitors the overall NIH Pragmatic Trials Collaboratory publications pipeline and proposes new topics for cross-Collaboratory publications. A cross-Collaboratory publication may be prepared by an ad hoc working group or by 1 or more Core Working Groups or Demonstration Project teams.

IV. Demonstration Project Publications and Presentations

A. Authorship

Decisions regarding the content and authorship of Demonstration Project publications and presentations will be made by the individual Demonstration Project steering committee, including NIH staff who provide oversight for the project (when allowed by NIH policy specific to the supporting Institute, Center, or Office).

B. Review

1. Demonstration Project **manuscripts** will be submitted by the authors to the Coordinating Center (nih-collaboratory@dm.duke.edu) at least 10 business days before the planned submission to allow Publications Committee staff to review the document to ensure the use of required acknowledgment language and to check for mentions of other Demonstration Projects. Committee staff will respond within 10 business days.

   Abstracts and presentations should acknowledge NIH Pragmatic Trials Collaboratory support but need not be submitted to the Coordinating Center in advance. See Section IX of this policy for funding acknowledgment language.

2. For draft Demonstration Project manuscripts that include descriptions of or details about a Demonstration Project other than the authors' own, committee staff will notify the Publications Committee chair and will share the manuscript or other materials with the other Demonstration Project principal investigator. That investigator will be given the opportunity to review the pertinent section for accuracy, comment on the portrayal of the Demonstration Project, and offer corrections of errors, but will not exercise editorial control over other sections of the manuscript. If no response is received from the principal investigator within 10 business days of receiving the manuscript for review, assent and approval will be assumed. In the event of disagreements between the author(s) and the other Demonstration Project principal investigator, the issue will be referred to the chair of the NIH Collaboratory Steering Committee for adjudication.

3. There may be circumstances (for example, if an author is an NIH staff member) wherein an NIH Institute, Center, or Office for a given Demonstration Project would require review of a manuscript, abstract, or presentation before its submission. Authors are expected to work with NIH

staff to determine whether such a review is required and, if so, to ensure that the requirement is addressed before submission.

4. Final editorial authority and the decision to publish will reside with the Demonstration Project steering committee, including NIH staff who provide oversight for the project. The Publications Committee will provide advice, suggestions, and assistance with dissemination as needed.

5. Other manuscripts, abstracts, and presentations arising from Demonstration Projects without specific aims of being designated as NIH Pragmatic Trials Collaboratory publications or presentations will be provided by Demonstration Project investigators in a listing submitted biannually to the Coordinating Center. The Demonstration Project investigator or Publications Committee chair may request that a manuscript be shared for comment due to high interest.

6. All Demonstration Project manuscripts submitted to the Coordinating Center before publication will remain confidential and will not be shared outside the Publications Committee membership and staff, Demonstration Project principal investigators (if applicable), Coordinating Center principal investigators, and the author(s).

C. After Publication or Presentation

1. Once a Demonstration Project manuscript, abstract, or presentation has been accepted for publication or presentation, the lead author or their designee will inform the Coordinating Center staff and provide them with a final copy of the accepted publication or presentation.

2. Demonstration Project principal investigators or their designees will submit quarterly updates to Coordinating Center about all publication and presentation activity related to the project.

V. Core Working Group Publications and Presentations

A. Authorship

Decisions regarding the content and authorship of Core Working Group publications and presentations will be made by the members of the Core Working Group(s) involved in creation of the work. All members of the respective Core Working Group(s) will be given an opportunity for comment. If 10 business days pass without feedback, assent to that version of the manuscript will be assumed.

B. Review

1. Core Working Group **manuscripts** will be submitted by the author(s) to the Coordinating Center (nih-collaboratory@dm.duke.edu) for delivery to the Publications Committee staff, who will have 10 business days to collect and forward comments and suggestions from (a) Core Working Group members, (b) Publications Committee members, and (c) any additional Coordinating Center members involved. There may be circumstances (for example, if an author is an NIH staff member) wherein an NIH Institute, Center, or Office would require review before submission. Authors are expected to work with NIH staff to determine whether such a review is required and, if so, to ensure that the requirement is addressed before submission.

   Abstracts and presentations should acknowledge NIH Pragmatic Trials Collaboratory support but need not be submitted to the Coordinating Center in advance. See Section IX of this policy for funding acknowledgment language.

2. For draft Core Working Group manuscripts that include descriptions of or details about a Demonstration Project, the Publications Committee staff will share the manuscript with the Demonstration Project principal investigator. The Demonstration Project principal investigator will be given the opportunity to review the pertinent section for accuracy, comment on the portrayal of the Demonstration Project, and offer corrections of errors, but will not exercise editorial control over other sections of the manuscript. If no response is received from the Demonstration Project principal investigator within 10 business days of receiving the manuscript for review, assent and approval will be assumed. In the event of disagreements between the author(s) and the Demonstration Project principal investigator, the issue will be referred to the chair of the NIH Collaboratory Steering Committee for adjudication.

3. An additional 10 days may be taken by the Publications Committee after comments are generated to adjudicate any resulting editorial changes.

   a. Where intractable differences of opinion remain, suggested changes from all sides will be forwarded to the designated coauthors.

   b. Comments from any Publications Committee member, NIH or otherwise, will not constitute official positions of the NIH.

4. Final editorial authority and the decision to publish will reside with the designated coauthors, although the Publications Committee will have the

right to vote on the designation of the final proposed manuscript as an NIH Pragmatic Trials Collaboratory publication or presentation.

a. Manuscripts, abstracts, and presentations that are not designated as NIH Pragmatic Trials Collaboratory publications or presentations will not be listed on the NIH Pragmatic Trials Collaboratory website and will not benefit directly from any public relations or news items published on the NIH Pragmatic Trials Collaboratory website.

5. In the event that authors of a publication must meet an impending deadline for a special issue or call for papers or respond to an invitation to submit within a brief period of time, authors should contact the Coordinating Center to request expedited review of the manuscript. If an expedited review is not possible before submission, the authors will send the manuscript to the Coordinating Center within 10 business days after submission; the Publications Committee will still consider whether the manuscript will be designated as an NIH Pragmatic Trials Collaboratory publication.

6. All Core Working Group manuscripts submitted to the Coordinating Center before publication will remain confidential and will not be shared outside the Publications Committee membership and staff, Demonstration Project principal investigators (if applicable), Coordinating Center principal investigators, and the author(s).

C. After Publication

Once a Core Working Group manuscript, abstract, or presentation has been accepted for publication or presentation, the lead author or their designee will inform the Coordinating Center staff, who will notify the NIH program official and the Publications Committee staff.

VI. Core Working Group Guidance Documents

A. Authorship

Decisions regarding the content and authorship of guidance documents will be made by the members of the Core Working Group(s) or ad hoc working group involved in creation of the work. All members of the respective working group(s) will be given an opportunity for comment. If 10 business days pass without feedback, assent to that version of the guidance document will be assumed.

B. Review

1. Guidance documents will be submitted by the author(s) to the Coordinating Center (nih-collaboratory@dm.duke.edu) for delivery to the Publications Committee staff, who will have 10 business days to collect and forward comments and suggestions from (a) working group members, (b) Publications Committee members, and (c) any additional Coordinating Center members involved. There may be circumstances (for example, if an author is an NIH staff member) wherein an NIH Institute, Center, or Office would require review before publication of the guidance document. Authors are expected to work with NIH staff to determine whether such a review is required and, if so, to ensure that the requirement is addressed before submission.

2. For guidance documents that include descriptions of or details about an ongoing or completed Demonstration Project, the Publications Committee staff will share the document with the Demonstration Project principal investigator. The Demonstration Project principal investigator will be given the opportunity to review the pertinent section for accuracy, comment on the portrayal of the Demonstration Project, and offer corrections of errors, but will not otherwise exercise editorial control over the document. If no response is received from the principal investigator within 10 business days of receiving the guidance document, assent and approval will be assumed. In the event of disagreements between the author(s) and the Demonstration Project principal investigator, the issue will be referred to the chair of the NIH Collaboratory Steering Committee for adjudication.

3. An additional 10 days may be taken by the Publications Committee after comments are generated to adjudicate any resulting editorial changes.

    a. Where intractable differences of opinion remain, suggested changes from all sides will be forwarded to the author(s).

    b. Comments from any Publications Committee member, NIH or otherwise, will not constitute official positions of the NIH.

4. Final editorial authority and the decision to publish the guidance document will reside with the author(s).

VII. Core Working Group Tools, Best Practice Documents, and Other Resources

A. Authorship

Decisions regarding the content (and authorship, if applicable) of tools, best practice documents, and other resources will be made by the members of the Core Working Group(s) or ad hoc working group involved in the creation of the work. All members of the respective Core Working Group(s) or ad hoc working group will be given an opportunity for comment. If 10 business days pass without feedback, assent to that version of the document will be assumed.

B. Review

1. Tools, best practice documents, and other resources will be submitted by the authors to the Coordinating Center (nih-collaboratory@dm.duke.edu) for delivery to Publications Committee staff at least 10 business days before publication to allow staff to review the document to ensure the use of required disclaimer language, if applicable, and to check for mentions of Demonstration Projects. The committee staff will respond within 10 business days.

2. For tools, best practice documents, and other resources that include descriptions of or details about an ongoing or completed Demonstration Project, committee staff will share the document with the Demonstration Project principal investigator. The Demonstration Project principal investigator will be given the opportunity to review the pertinent section for accuracy, comment on the portrayal of the Demonstration Project, and offer corrections of errors, but will not exercise editorial control over other sections of the document. If no response is received from the principal investigator within 10 business days of receiving the document, assent and approval will be assumed. In the event of disagreements between the author(s) and the Demonstration Project principal investigator, the issue will be referred to the chair of the NIH Collaboratory Steering Committee for adjudication.

3. There may be circumstances (for example, if an author is an NIH staff member) wherein an NIH Institute, Center, or Office for a given Demonstration Project would require review of a best practice document before its publication. Authors are expected to work with NIH staff to determine whether such a review is required and, if so, to ensure that the requirement is addressed before publication.

4. Final editorial authority and the decision to publish will reside with the authors.

VIII. Short Communications by the Coordinating Center

Short communications are produced by the Coordinating Center communications team in consultation with the Coordinating Center leadership. They are prepared in accordance with the Coordinating Center staff's relevant operational processes.

IX. Acknowledgment of NIH Pragmatic Trials Collaboratory Support

1. All manuscripts, abstracts, and presentations **derived from the work of one or more Core Working Groups or the Coordinating Center** should include the following acknowledgment:

   "This work was supported within the National Institutes of Health (NIH) Pragmatic Trials Collaboratory through cooperative agreement U24AT009676 from the National Center for Complementary and Integrative Health (NCCIH), the National Institute of Allergy and Infectious Diseases (NIAID), the National Cancer Institute (NCI), the National Institute on Aging (NIA), the National Heart, Lung, and Blood Institute (NHLBI), the National Institute of Nursing Research (NINR), the National Institute of Minority Health and Health Disparities (NIMHD), the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), the NIH Office of Behavioral and Social Sciences Research (OBSSR), and the NIH Office of Disease Prevention (ODP). This work was also supported by the NIH through the NIH HEAL Initiative under award number U24AT010961. [If supplemental funding was provided for specific activities, then the Institute, Center, or Office providing the support should be acknowledged here.] The content is solely the responsibility of the authors and does not necessarily represent the official views of the NCCIH, NIAID, NCI, NIA, NHLBI, NINR, NIMHD, NIAMS, OBSSR, or ODP, or the NIH or its HEAL Initiative."

2. Manuscripts, abstracts, and presentations derived from one or more Demonstration Projects:

   a. All manuscripts, abstracts, and presentations **derived from one or more NIH Pragmatic Trials Collaboratory Demonstration Projects** should include the following acknowledgment:

      "This work was supported within the National Institutes of Health

(NIH) Pragmatic Trials Collaboratory by cooperative agreement [UG3/UH3 grant number] from the [Institute, Center, or Office providing funding or oversight]. This work also received logistical and technical support from the NIH Pragmatic Trials Collaboratory Coordinating Center through cooperative agreement U24AT009676 from the National Center for Complementary and Integrative Health (NCCIH), the National Institute of Allergy and Infectious Diseases (NIAID), the National Cancer Institute (NCI), the National Institute on Aging (NIA), the National Heart, Lung, and Blood Institute (NHLBI), the National Institute of Nursing Research (NINR), the National Institute of Minority Health and Health Disparities (NIMHD), the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), the NIH Office of Behavioral and Social Sciences Research (OBSSR), and the NIH Office of Disease Prevention (ODP). The content is solely the responsibility of the authors and does not necessarily represent the official views of [Institute, Center, or Office providing funding or oversight] or the NCCIH, NIAID, NCI, NIA, NHLBI, NINR, NIMHD, NIAMS, OBSSR, or ODP, or the NIH."

b. All manuscripts, abstracts, and presentations **derived from one or more PRISM Demonstration Projects** should include the following acknowledgment:

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3. Manuscripts, abstracts, and presentations supported by both the Coordinating Center and one or more Demonstration Projects (UG3/UH3):

a. All manuscripts, abstracts, and presentations **supported by the Coordinating Center and one or more NIH Pragmatic Trials Collaboratory Demonstration Projects** should include the following acknowledgment:

"This work was supported within the National Institutes of Health

(NIH) Pragmatic Trials Collaboratory through cooperative agreement U24AT009676 from the National Center for Complementary and Integrative Health (NCCIH), the National Institute of Allergy and Infectious Diseases (NIAID), the National Cancer Institute (NCI), the National Institute on Aging (NIA), the National Heart, Lung, and Blood Institute (NHLBI), the National Institute of Nursing Research (NINR), the National Institute of Minority Health and Health Disparities (NIMHD), the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), the NIH Office of Behavioral and Social Sciences Research (OBSSR), and the NIH Office of Disease Prevention (ODP), and through cooperative agreement [UG3/UH3 grant number] from the [Institute, Center, or Office providing funding or oversight]. This work was also supported by the NIH through the NIH HEAL Initiative under award number U24AT010961. [If supplemental funding was provided for specific activities, then the Institute, Center, or Office providing the support should be acknowledged here.] The content is solely the responsibility of the authors and does not necessarily represent the official views of the [Institute, Center, or Office providing funding or oversight] or the NCCIH, NIAID, NCI, NIA, NHLBI, NINR, NIMHD, NIAMS, OBSSR, or ODP, or the NIH or its HEAL Initiative."

b. All manuscripts, abstracts, and presentations **supported by the Coordinating Center and one or more PRISM Demonstration Projects** should include the following acknowledgment:

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support should be acknowledged here.] The content is solely the responsibility of the authors and does not necessarily represent the official views of the [Institute, Center, or Office providing funding or oversight] or the NCCIH, NIAID, NCI, NIA, NHLBI, NINR, NIMHD, NIAMS, OBSSR, or ODP, or the NIH or its HEAL Initiative."

4. Manuscripts that cite **multiple sources of support** (for example, a project supported by the Coordinating Center and one or more NIH Institutes, Centers, or Offices) should list funding sources in declining order of proportional support for the given project.

5. Before issuing a press release concerning results, presentations, or publications derived from this research, authors should notify the relevant NIH Institute, Center, or Office in advance to allow for coordination.

SEASONED PROJECTS STUDY SNAPSHOTS

NIH PRAGMATIC TRIALS COLLABORATORY

Rethinking Clinical Trials®

ABATE Infection Project

Active Bathing to Eliminate (ABATE) Infection

Principal Investigator
Susan Huang, MD, MPH

ClinicalTrials.gov Identifier
NCT02063867

Sponsoring Institution
University of California, Irvine

Collaborators
- HCA Healthcare
- Harvard Medical School/Harvard Pilgrim Health Care
- University of California, Irvine School of Medicine
- Rush University
- John H. Stroger Hospital
- Centers for Disease Control and Prevention

NIH Institute Providing Oversight
National Institute of Allergy and Infectious Diseases (NIAID)

DATA AND RESOURCE SHARING

- **Data sharing checklist**
- **Data request**
- **Primary study results:** Huang SS, Septimus E, Kleinman K, et al. Chlorhexidine versus routine bathing to prevent multidrug-resistant organisms and all-cause bloodstream infections in general medical and surgical units (ABATE Infection trial): a cluster-randomised trial. *Lancet*. 2019;393(10177):1205-1215. PMID: 30850112.

STUDY AT A GLANCE

STUDY QUESTION AND SIGNIFICANCE

Universal antiseptic bathing and nasal decolonization are known to reduce bloodstream infections and multidrug-resistant organisms in intensive care unit (ICU) settings. However, the effects of this type of decolonization outside the ICU are unknown. The objective of the study was to evaluate the use of universal chlorhexidine bathing plus targeted nasal decolonization for methicillin-resistant *Staphylococcus aureus* (MRSA) carriers in hospitalized patients outside the ICU.

DESIGN AND SETTING

Cluster randomized trial in 53 hospitals with 194 non–critical care units, of which 26 hospitals (with 90 non–critical care units) were randomly assigned to routine care and 27 hospitals (with 104 non–critical care units) were randomly assigned to the intervention.

INTERVENTION AND METHODS

The intervention included daily chlorhexidine bathing for all patients in the unit plus nasal mupirocin for known MRSA carriers. The primary outcome was MRSA or vancomycin-resistant enterococcus (VRE) clinical cultures attributed to participating units. The primary analysis was an unadjusted intention-to-treat analysis using proportional hazards models that accounted for clustering within hospitals. The analysis assessed whether the hazard ratio between the intervention and baseline periods differed significantly between study groups. Clinical cultures of multidrug-resistant, gram-negative bacteria and all-cause bloodstream infection were evaluated as secondary outcomes.

FINDINGS

Universal decolonization did not reduce multidrug-resistant bacteria or bloodstream infection in the overall non-ICU population. In a post hoc analysis of patients with medical devices, decolonization was associated with a significant 32% reduction in all-cause bloodstream infections and a significant 37% reduction in MRSA or VRE clinical cultures attributable to participating units. Targeting patients with devices may be particularly valuable because they represented 10% of the non-ICU population but were responsible for 37% of all MRSA and VRE clinical cultures and 56% of all bloodstream infections in non-ICU patients.

CONCLUSIONS AND RELEVANCE

Universal decolonization and targeted nasal decolonization did not significantly reduce the risk of multidrug-resistant infections in the overall non–critically ill patient population, but large reductions were seen in the subset of patients with medical devices.

rethinkingclinicaltrials.org

GENERALIZABLE LESSONS

Challenge	Solution
Hospital quality improvement initiatives that could compete with the trial intervention and influence trial outcomes	Monthly tracking of quality improvement initiatives in both study arms and review with Steering Committee; and encouragement of hospitals considering competing interventions to delay implementation, narrow implementation to non-trial units, or withdraw from the trial
Changes in hospital leadership and changes in nomenclature of units in electronic health system, which is needed to identify participating locations	Requests during monthly coaching calls for study champions to disclose changes in leadership or contact information and changes in unit names or patient composition
Greater need for data cleaning and standardization in trials with very large datasets, and idiosyncratic differences between sites not amenable to economy of scale for data cleaning	Budgeting of increased programming effort for data cleaning, standardization, and analysis
Requirement to have dedicated ethical oversight for any prisoner admitted to non-ICU area during the course of the trial, despite meeting minimal risk criteria	Identification of participating site with prisoner representative on IRB to provide oversight

"Quality improvement initiatives are integral and common to healthcare. Tracking, discussing, and delaying competing interventions is critical to assuring participants, investigators, and stakeholders that the trial question can be answered." — Susan Huang

"While every trial has different data issues, it was incredibly helpful within the Collaboratory to discuss data cleaning and standardization issues as a common and integral part of any trial. It is worthwhile for the Collaboratory to continue to right-size expectations for data cleaning and analysis for large pragmatic trials." — Susan Huang

"We did not encounter a major barrier to finding an oversight committee with a prisoner representative, but this experience raised the question of how to enable minimum-risk quality improvement research for all vulnerable groups without requiring dedicated oversight."

— Susan Huang

ADDITIONAL RESOURCES

- Article: Calculating Power by Bootstrap, With an Application to Cluster-Randomized Trials
- Video interview: Dr. Huang Discusses the ABATE Infection Project
- NIH Pragmatic Trials Collaboratory Grand Rounds: ABATE Infection Trial: Backstage Tour
- NIH Pragmatic Trials Collaboratory Steering Committee Meeting Presentation: ABATE Infection Trial: Barriers and Lessons Learned

Access the complete set of ABATE Infection resources.

NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

ACP PEACE

Advance Care Planning: Promoting Effective and Aligned Communication in the Elderly (ACP PEACE)

Principal Investigators
James A. Tulsky, MD, and Angelo Volandes, MD, MPH

Sponsoring Institution
Dana-Farber Cancer Institute

Collaborators
- Massachusetts General Hospital
- Boston Medical Center
- Duke University
- Feinstein Institute for Medical Research (Northwell Health)
- Mayo Clinic

NIH Institute Providing Oversight
National Institute on Aging (NIA)

Program Official
Marcel E. Salive, MD, MPH (NIA)

Project Scientist
Karen Kehl, PhD, RN, FPCN (National Institute of Nursing Research [NINR])

ClinicalTrials.gov Identifier
NCT03609177

ABSTRACT

Too many older Americans with advanced cancer die every year receiving aggressive interventions at the end of life that do not reflect their values, goals, and preferences. Advance care planning (ACP) is the most consistent modifiable factor associated with better end-of-life communication and goal-concordant care. However, clinicians often do not possess the communication skills needed for high-quality ACP conversations, and patients are often unable to imagine their options for medical care to make informed decisions.

The ACP PEACE Demonstration Project combines two well-tested, evidence-based complementary interventions: clinician communication skills training (VitalTalk) and patient video decision aids (ACP Decisions). This approach treats patients and clinicians as equal stakeholders, providing both with the communication skills and tools needed to optimally make informed decisions before the toughest choices arise. ACP PEACE is a pragmatic, cluster-randomized, stepped-wedge trial that will be conducted in three large healthcare systems. The study will use established electronic health record (EHR) systems at each health system to obtain outcomes. It is proposed that a higher proportion of patients in the intervention arm will complete advance care plans, have documented electronic medical orders for resuscitation preferences, be seen in palliative care consultations, and enroll in hospice. The ACP PEACE study will monitor long-term outcomes to evaluate whether patients received the care they planned for and wanted.

WHERE CAN ACP VIDEOS BE VIEWED?

View at Home

View in a Clinical Setting

WHAT WE'VE LEARNED SO FAR

Challenge	Solution
Most clinicians do not use the structured variable in the EHR that the study team planned to use to extract the primary outcome.	The study team developed a workaround that uses natural language processing to abstract the primary outcome from the free text of the clinical note in the EHR.
Some participating health systems have not established a method for patients to opt out of having their deidentified data used for research purposes.	The study team plans to use a "broadcast notification" that displays posters or other notices in healthcare settings that let patients know they can opt out if they have a concern about their deidentified data being shared for research purposes.

"Make sure you get appropriate buy-in from enough stakeholders to know that you're going to get the project done."

SELECTED PUBLICATIONS & PRESENTATIONS

- Presentation: Presentation to the NIH Pragmatic Trials Steering Committee (2023)
- Video Interview: Update on the ACP PEACE Demonstration Project (2022)
- Publication: Reaching Ambulatory Older Adults with Educational Tools: Comparative Efficacy and Cost of Varied Outreach Modalities in Primary Care (2023)
- Publication: Association of an Advance Care Planning Video and Communication Intervention With Documentation of Advance Care Planning Among Older Adults: A Nonrandomized Controlled Trial (2022)
- Publication: A Yet Unrealized Promise: Structured Advance Care Planning Elements in the Electronic Health Record (2021)
- Publication (Study Design): Advance Care Planning: Promoting Effective and Aligned Communication in the Elderly (ACP-PEACE): The Study Protocol for a Pragmatic Stepped-Wedge Trial of Older Patients With Cancer (2020)

Access the complete set of ACP PEACE resources.

NIH PRAGMATIC TRIALS COLLABORATORY

Rethinking Clinical Trials®

BACK IN ACTION

Pragmatic Trial of Acupuncture for Chronic Low Back Pain in Older Adults (BackInAction)

Principal Investigators
Andrea J. Cook, PhD; Lynn DeBar, PhD, MPH

Sponsoring Institution
Kaiser Foundation Research Institute, Seattle, WA

Collaborators
- Kaiser Permanente Department of Research, Oakland, CA
- Sutter Health Research Institute, Palo Alto, CA
- Institute of Family Health, New York, NY
- RAND Corporation, Santa Monica, CA

NIH Institute Providing Oversight
National Center for Complementary and Integrative Health (NCCIH)

Program Official
Lanay Mudd, PhD (NCCIH)

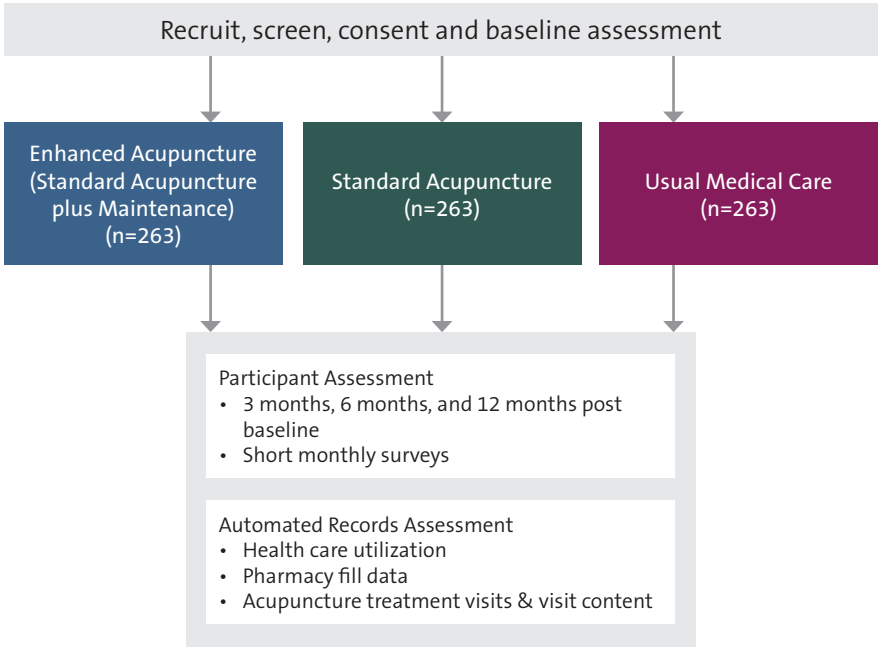
Project Scientist
Basil Eldadah, MD, MPH (National Institute on Aging)

ClinicalTrials.gov Identifier
NCT04982315

ABSTRACT

A critical gap exists in evidence about the safety and effectiveness of treatments for older adults with chronic low back pain (cLBP). Acupuncture has been found to be effective in treating cLBP in younger adults, yet trials have rarely included older adults, who have more comorbidities and may respond differently from typical trial participants. The implementation phase of BackInAction (formerly known as AcuOA) will consist of a 3-arm trial of 789 adults ≥65 years of age with cLBP to compare a standard 12-week course of acupuncture, an enhanced course of acupuncture, and usual medical care. The primary outcome will be back-related function at 26 weeks. The expectation is that back-related function in older adults with cLBP will be most improved among participants in the enhanced acupuncture arm, followed by the standard acupuncture arm, and least improved among those receiving only usual care.

The large study sample will be recruited from 4 diverse health plans to represent the ethnic and racial composition of Medicare enrollees as well as the most common ways acupuncture is incorporated in insurance-based care for chronic pain. If successful, this pragmatic randomized clinical trial will offer clear guidance about the value of acupuncture for improving functional status and reducing pain intensity and pain interference for older adults with cLBP. This evidence also will provide important information to Medicare about the value of acupuncture for their beneficiaries and for individual physicians and patients deciding on a course of treatment.



WHAT WE'VE LEARNED SO FAR

Challenge	Solution
Completing all aspects of the single IRB oversight process took longer than expected.	The study team worked closely with leadership of the IRB to address delays and barriers. It was important to allow sufficient time to assemble study materials (such as consent forms, data collection forms, recruitment materials) in order to move forward with IRB approval.
The requirement to use the HEAL Initiative's Common Domain Elements (CDEs) increased redundancy in our proposed questionnaire and was not completely pertinent to our population of older adults.	The team modified some CDEs and dropped some PROMIS-29 secondary and tertiary outcomes and other questions in order to reduce redundancies.
The Centers for Medicare and Medicaid Services (CMS) decided to move forward with reimbursing for acupuncture treatment for older adults with low back pain, which may have an impact on the community acupuncturists treating these patients.	The study team considers this to be an ongoing process and is closely monitoring CMS decisions. The team anticipates a potential need to tailor the study and to understand the impact on real-world care and ramifications for the generalizability of the trial's approach and findings.

"A pragmatic trial allows us to ask questions that are valuable to the older adult population."

SELECTED PUBLICATIONS & PRESENTATIONS

- Presentation: Presentation to the NIH Pragmatic Trials Collaboratory Steering Committee (2023)
- Article (Study Design): Acupuncture for Chronic Low Back Pain in Older Adults: Design and Protocol for the BackInAction Pragmatic Clinical Trial (2023)
- Poster: Who Says Older Folks Aren't Tech-Savvy? Experience With a Fully Electronic Consent Procedure in a Trial With Older Adults (2023)

Access the complete set of BackInAction resources.

NIH PRAGMATIC TRIALS COLLABORATORY

Rethinking Clinical Trials®

FM-TIPS
Fibromyalgia TENS In Physical Therapy Study

Fibromyalgia TENS in Physical Therapy Study (FM-TIPS)

Principal Investigators
Kathleen Sluka, PT, PhD; and Leslie Crofford, MD

Sponsoring Institution
University of Iowa

Collaborators
- Advanced Physical Therapy and Sports Medicine
- Genesis Healthcare Systems
- Kepros Physical Therapy and Performance
- Rock Valley Physical Therapy
- University of Illinois Chicago

NIH Institute Providing Oversight
National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)

Program Official
Charles Washabaugh, PhD (NIAMS)

Project Scientist
Joe Bonner, PhD (National Institute of Child Health and Human Development/National Center for Medical Rehabilitation Research)

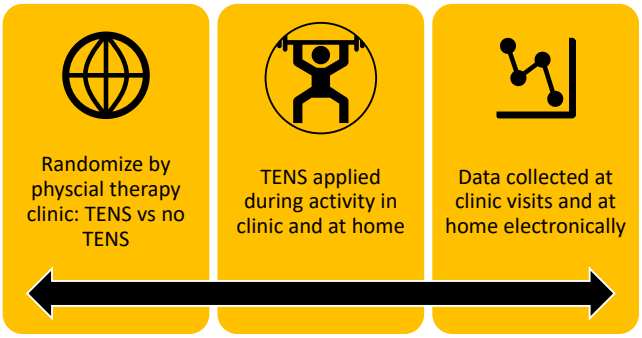
ClinicalTrials.gov Identifier
NCT04683042

Study Website
FM-TIPS

ABSTRACT

Fibromyalgia is a chronic pain condition characterized by widespread musculoskeletal pain, tenderness, and stiffness associated with fatigue and sleep disturbance. The goal of reducing opioid use in patients with chronic pain requires that proven nonpharmacologic treatments are applied in clinical practice. We have recently completed a trial that conclusively demonstrated the efficacy of transcutaneous electrical nerve stimulator (TENS) for reducing musculoskeletal pain. While physical therapists are trained in the use of TENS, it is underused in clinical practice. The FM-TIPS Demonstration Project is an embedded pragmatic trial that will compare the effectiveness of physical therapy with or without the addition of TENS for patients with fibromyalgia within physical therapy clinics. The aims of the trial are to demonstrate the feasibility of adding TENS to the treatment of patients with fibromyalgia in a real-world practice setting and to determine if the addition of TENS reduces pain, increases adherence to physical therapy, and allows patients to reach their specific functional goals with less medication use.

FM-TIPS will address the critical need for strategies that implement effective nonpharmacologic treatments for fibromyalgia. Successful completion of this trial will provide generalizable effectiveness data for referring providers, physical therapists, and insurers and will inform future pragmatic trials of nonpharmacologic treatments conducted in physical therapy practices.



WHAT WE'VE LEARNED SO FAR

Challenge	Solution
In order to deliver the FM-TIPS intervention, physical therapy clinicians needed to receive clinical research certification (eg, CITI training), which was a time-consuming step.	The study team worked with the IRB to find options for online training and webinars for clinicians to help streamline the required certification.
The process for collecting patient-reported outcomes (PROs) had to be adjusted to accommodate a transition of the primary outcome to a home test.	The study team met with the Collaboratory's Patient-Centered Outcomes (PCO) Core to find a way to validate the test for movement-evoked pain (primary outcome) to be conducted online at home by the participant.
Making adjustments due to the onset of the COVID-19 pandemic affected the timing of contracts and the partnership of one healthcare system.	The study team developed a COVID-19 response plan for potential pauses in enrollment or use of telehealth by clinicians.
Incorporating the core domain elements (CDE) for the HEAL Initiative led to changes in data extraction.	The study team collected more PRO measures instead of extracting from the EHR.

"We want to make it easy for the clinician to choose nonpharmacologic strategies for treating pain that improve both symptom and function in patients with fibromyalgia."

SELECTED PUBLICATIONS & PRESENTATIONS

- Presentation: Presentation to the NIH Pragmatic Trials Collaboratory Steering Committee (2023)
- Article (Study Design): The Fibromyalgia Transcutaneous Electrical Nerve Stimulation in Physical Therapy Study Protocol: A Multisite Embedded Pragmatic Trial (2022)

Access the complete set of FM-TIPS resources.

NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

Intelligent Stewardship Prompts to Improve Real-Time Empiric Antibiotic Selection for Patients Trials for Abdominal and Skin and Soft Tissue Infections (INSPIRE)

Principal Investigators
Susan S. Huang, MD, MPH
Richard Platt, MD, MSc

Lead Investigator
Shruti Gohil, MD, MPH

Sponsoring Institution
Harvard Pilgrim Health Care

Healthcare System Partner
HCA Healthcare

Collaborators
- HCA Healthcare
- University of California, Irvine
- Brigham and Women's Hospital
- University of Massachusetts Amherst
- Rush University

NIH Institute Providing Oversight
National Institute of Allergy and Infectious Diseases (NIAID)

Program Official and Project Scientist
Clayton Huntley, PhD (NIAID)

ClinicalTrials.gov Identifiers
INSPIRE-ASP Trial for Abdominal Infections: NCT05423743
INSPIRE-ASP Trial for Skin and Soft Tissue Infections: NCT05423756

ABSTRACT

The INSPIRE Demonstration Project consists of the INSPIRE-ASP Trials for Abdominal and Skin and Soft Tissue Infections, 2 cluster randomized trials using personalized clinical decision support to improve judicious antibiotic prescribing for non–critically ill patients hospitalized with abdominal infections or skin and soft tissue infections. More than half of non–critically ill patients with these infections receive extended-spectrum antibiotics, though fewer than 5% have an antibiotic-resistant pathogen. The goal of the trials is to advise physicians to prescribe either standard-spectrum or extended-spectrum empiric antibiotics on the basis of an algorithm that estimates each patient's personalized probability of having an antibiotic-resistant infection. This personalized probability is based on routinely collected patient information in the electronic health record (EHR) and the local prevalence of resistant organisms in abdominal or skin and soft tissue infections. The trials will compare routine care under hospital-based antibiotic stewardship programs with an enhanced program using the predictive algorithm plus audit and feedback to reduce unnecessary empiric prescribing of extended-spectrum antibiotics. The study team will first develop disease-specific prediction algorithms for abdominal infections and skin and soft tissue infections. The study team will then integrate the predictive algorithm into the computerized provider order entry (CPOE) system to prompt physicians when the antibiotic they select is discordant with the estimated need for that antibiotic. Physicians will be prompted to use a standard-spectrum antibiotic when the risk of an antibiotic-resistant infection is low. More than ninety hospitals have been randomly assigned to routine care or to the CPOE prompt intervention plus audit and feedback. The 18-month study will evaluate approximately 53,000 patients with abdominal infections and approximately 37,000 patients with skin and soft tissue infections. The trials will evaluate the ability of the intervention to reduce unnecessary extended-spectrum antibiotics while maintaining good clinical outcomes as measured by length of stay and transfer to an intensive care unit. The methods will be readily applicable to other EHR-based prescribing systems.

NIH PRAGMATIC TRIALS COLLABORATORY

Rethinking Clinical Trials®

Nonpharmacologic Options in Postoperative Hospital-based and Rehabilitation Pain Management (NOHARM)

Principal Investigators
Andrea Cheville, MD; Jon Tilburt, MD

Sponsoring Institution
Mayo Clinic Rochester, MN

Collaborators
- Mayo Clinic Rochester
- Mayo Clinic Florida
- Mayo Clinic Arizona
- Mayo Clinic Upper Midwest Health System

NIH Institute Providing Oversight
National Institute on Aging (NIA)

Program Official
Marcel Salive, MD (NIA)

Project Scientist
Theresa Cruz, PhD (National Institute of Child Health and Human Development [NICHD])

ClinicalTrials.gov Identifier
NCT04570371

ABSTRACT

Prescriptions for narcotic pain relief after surgery result in unintended prolonged opioid use for hundreds of thousands of Americans. That trend fuels an excess supply of opioids that can lead to dependence, addiction, diversion, and overdoses on a national scale. Nonpharmacologic pain care is effective and recommended by guidelines for perioperative pain while offering a more favorable risk-benefit ratio. However, nonpharmacologic pain care is rarely used as first- or second-line therapy after surgery. Patient and clinician decision support interventions are effective in encouraging patient-centered and guideline-concordant care, but these strategies have not been tested pragmatically as a bundle in everyday postoperative pain care.

The NOHARM trial will test an EHR-embedded, bundled intervention comprised of patient- and clinician-facing decision support components that enable patients to integrate nonpharmacologic pain care (NPPC) into their perioperative management. NOHARM will employ a stepped-wedge, cluster-randomized pragmatic clinical trial design. Clusters throughout Mayo Clinic Enterprise spanning 6 institutions in 4 states will participate. The NOHARM trial will evaluate whether pain and function, assessed with PROMIS tools, can be improved while honoring patient values and deemphasizing opioids in pain management.

WHAT WE'VE LEARNED SO FAR

Challenge	Solution
Accurately identifying and assigning the intervention to eligible patients within the electronic health record (EHR) in an automated way	The study implemented appropriate ordering, referring, and prescribing (ORP) codes for automatic assignment.
Helping clinic staff know which patients are enrolled in the NOHARM trial	The study added a banner in the Epic system to help clinical teams easily identify NOHARM patients.
Identifying and accounting for the number and variability of clusters based on size, geography, and median pain burden of the patient population	The team worked with the Collaboratory's Biostatistics and Study Design Core to plan a "constrained randomization" design, which will help with managing varied cluster sizes, geographic locations, and practice volumes as part of the stepped-wedge cluster-randomized trial.
Modifying the primary outcome measure due to incomplete ascertainment	The team determined that pain interference and physical function measures would be co-primary endpoints at 1, 2, and 3 months.

"We are excited to bring our novel use of the EHR as a critical and central intervention component and to bring that approach to the Collaboratory so we can both teach and learn."

SELECTED PUBLICATIONS & PRESENTATIONS

- Presentation: Presentation to the NIH Pragmatic Trials Collaboratory Steering Committee (2023)
- Article (Study Design): Non-pharmacological Options in Postoperative Hospital-Based and Rehabilitation Pain Management (NOHARM): Protocol for a Stepped-Wedge Cluster-Randomized Pragmatic Clinical Trial (2022)
- PCT Grand Rounds Presentation: Learning While Sprinting: A One-Year Retrospective from the NOHARM Pragmatic Trial (2020)

Access the complete set of NOHARM resources.

NIH PRAGMATIC TRIALS COLLABORATORY

Rethinking Clinical Trials®

Nudge

Personalized Patient Data and Behavioral Nudges to Improve Adherence to Chronic Cardiovascular Medications (Nudge)

Principal Investigators
Michael Ho, MD, PhD; and Sheana Bull, PhD, MPH

Sponsoring Institution
University of Colorado

ClinicalTrials.gov Identifier
NCT03973931

Collaborators
- UCHealth
- Denver Health
- VA Eastern Colorado Health Care System

NIH Institute Providing Oversight
National Heart, Lung, and Blood Institute (NHLBI)

Program Official
Lawrence Fine, MD, DrPH (NHLBI)

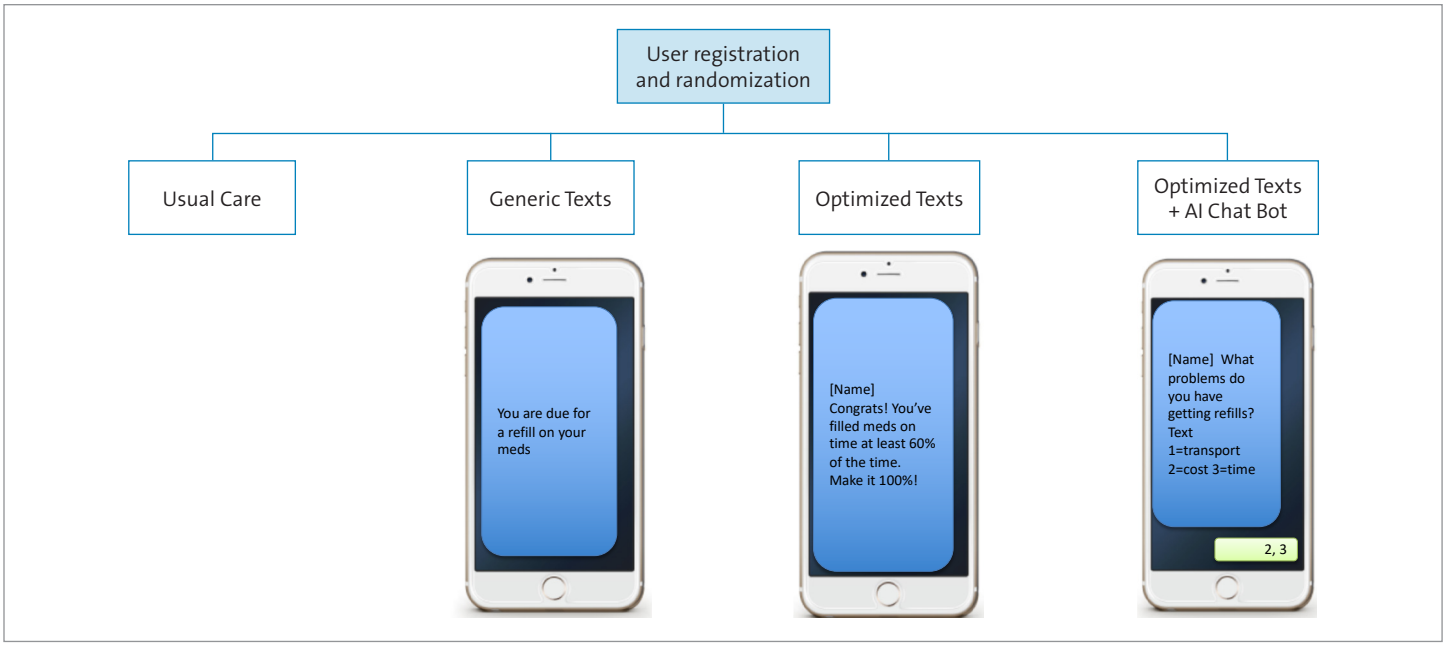
Project Scientist
Nicole Redmond, MD, PhD, MPH (NHLBI)

ABSTRACT

Nearly half of patients do not take their cardiovascular medications as prescribed, resulting in increased morbidity, mortality, and healthcare costs. Interventions to improve adherence—such as patient education, reminders, pharmacist support, and financial incentives—have produced inconsistent results due to limited study designs. Mobile and digital technologies for health promotion and disease self-management offer an opportunity to adapt behavioral "nudges" using ubiquitous mobile phone technology to facilitate medication adherence.

The Nudge Demonstration Project will use population-level pharmacy data to deliver nudges via mobile phone text messaging and an artificial intelligent (AI) interactive chat bot with the goal of improving medication adherence and patient outcomes in 3 integrated healthcare delivery systems. During the planning phase, the Nudge study team developed and piloted a technology-based nudge message library and a chat bot library of optimized interactive content for a range of diverse patients. Patients of interest are those with chronic cardiovascular conditions who take medications to treat hypertension, atrial fibrillation, coronary artery disease, diabetes, or hyperlipidemia. Episodes of nonadherence to prescribed medications are identified through gaps in medication refills. Participants are randomized to one of 4 study arms: usual care (no intervention), generic nudge (text reminder), optimized nudge, and optimized nudge plus intereactive AI chat bot.

INTERVENTION ARMS FOR THE PRAGMATIC TRIAL



WHAT WE'VE LEARNED SO FAR

Challenge	Solution
Some health systems did not consistently record cell phone numbers in the appropriate place, resulting in cell phone numbers not being imported in the research database.	Study team worked with an EPIC analyst to import cell phone numbers into the research database.
There were challenges in comparing definitions (eg, hospitalization) and nuances in how data are captured (eg, inpatient versus outpatient labs).	A team of analysts identified limitations across each system and worked with clinicians on the study team to create variable definitions compatible at each health system.
Due to a contractual issue, the study team was not able to obtain pharmacy data at one participating health system.	Team decided to delay enrollment of patients for at least 1 year at that health system and re-assess whether enrollment will be possible at the health system after they obtain more data. They will increase enrollment at the other 2 systems.

"Ideally, if people are doing a better job of refilling their meds, they can stay more adherent to their medications, and ultimately, have better health outcomes."

SELECTED PUBLICATIONS & PRESENTATIONS

- Article (Study Design): The NUDGE Trial Pragmatic Trial to Enhance Cardiovascular Medication Adherence: Study Protocol for a Randomized Controlled Trial (August 2021)
- Article: Leave Me Out: Patients' Characteristics and Reasons for Opting Out of a Pragmatic Clinical Trial Involving Medication Adherence (December 2021)
- Presentation: Presentation to the NIH Pragmatic Trials Collaboratory Steering Committee (May 2023)

NIH PRAGMATIC TRIALS COLLABORATORY

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Collaborative Care for Chronic Pain in Primary Care (PPACT)

Principal Investigator
Lynn DeBar, PhD

ClinicalTrials.gov Identifier
NCT02113592

Sponsoring Institution
Kaiser Permanente Center for Health Research

Collaborators:
- Kaiser Permanente regional health systems in Georgia, Northwest, and Hawaii
- Oregon Health and Science University

NIH Institutes Providing Oversight
- National Institute of Neurological Disorders and Stroke (NINDS)
- National Institute on Drug Abuse (NIDA)

DATA AND RESOURCE SHARING

- Data sharing checklist
- **Primary study results:** DeBar L, Mayhew M, Benes L, et al. A primary care-based cognitive behavioral therapy intervention for long-term opioid users with chronic pain: a randomized pragmatic trial. Ann Intern Med. 2022 Jan;175(1):46-55. doi: 10.7326/M21-1436. PMID: 34724405.

STUDY AT A GLANCE

STUDY QUESTION AND SIGNIFICANCE

Chronic pain is common, disabling, and costly. Few clinical trials have examined the use of cognitive behavioral therapy (CBT) interventions in primary care settings to improve chronic pain among patients who are receiving long-term opioid therapy.

DESIGN AND SETTING

Pragmatic, cluster randomized trial with 850 adult patients on long-term opioid therapy and receiving care in primary care clinics in 3 Kaiser Permanente healthcare regions from 2014 through 2016.

INTERVENTION AND METHODS

The study tested implementation of a CBT intervention that included pain self-management skills and yoga-based adapted movement in 12 weekly, 90-minute groups taught by an interdisciplinary team versus usual care. The primary outcome was self-reported pain as measured by the Pain, Enjoyment, General Activity (PEG) scale assessed quarterly over 12 months. Secondary outcomes included pain-related disability, satisfaction with care, and opioid and benzodiazepine use based as reflected in electronic health record data.

FINDINGS

After 12 months, the intervention group experienced greater reductions on all self-reported outcomes. At 6 months, the intervention group reported higher satisfaction with primary care. Benzodiazepine use decreased more in the intervention group, but opioid use did not differ significantly between the study groups.

CONCLUSIONS AND RELEVANCE

A collaborative care intervention for chronic pain consisting of primary care–based CBT using frontline clinicians resulted in modest but sustained reductions in measures of pain and pain-related disability compared with usual care but did not reduce the use of opioid medications.

GENERALIZABLE LESSONS

Challenge	Solution
Changes in leadership and variable understanding of how the study was aligned with opioid-tapering quality improvement efforts	The study team conducted significant formative research and communicated regularly with health plan and clinical leaders to track changes and account for the dynamic nature of usual care.
Hiring and retention of frontline staff; coordination, communication, and partnership with pain-related services and providers in settings where the study team worked	The study team made less use of clinic-based staff and greater use of traveling teams for delivery of interdisciplinary teams to provide the intervention (as well as more telephone work and flexibility with regard to the degree to which those from each core discipline were represented on intervention teams).
Irregular collection of data on pain intensity and interference for patients on long-term opioid treatment plans in healthcare systems	The study team set up a partially automated, tiered system for collection of patient-reported outcome (PRO) data with an email push through the patient portal, followed by an interactive voice response (IVR) call if there was no response to the email. Live, in-person follow-up was reserved for situations when there was no response to the email and IVR attempts at PRO data collection. (See Owen-Smith et al.)

"We appreciated the Collaboratory's general atmosphere of camaraderie and willingness to be honest about challenging issues and share suggestions with other study teams. The Coordinating Center was a means of connecting us all, and we learned a lot from others, including those working in very different scientific domains."

— Dr. Lynn DeBar

"For those planning to rely heavily on PROs, consider setting up an automated approach to data collection and follow-up, and keep the PROs short and clinically informative. PROs focused on function can be more useful for clinicians and easier for the study team to deliver. These kinds of win-wins for the healthcare system and the study team really help."

— Dr. Lynn DeBar

ADDITIONAL RESOURCES

- Article: Interdisciplinary Team-Based Care for Patients With Chronic Pain on Long-Term Opioid Treatment in Primary Care (PPACT) - Protocol for a Pragmatic Cluster Randomized Trial
- Article: Development and Assessment of a Crosswalk Between ICD-9-CM and ICD-10-CM to Identify Patients With Common Pain Conditions
- Article: Taking Opioids in Times of Crisis: Institutional Oversight, Chronic Pain and Suffering in an Integrated Healthcare Delivery System in the U.S.
- Article: Interactive Group-Based Orientation Sessions: A Method to Improve Adherence and Retention in Pragmatic Clinical Trials
- Article: Identifying Multisite Chronic Pain With Electronic Health Records Data
- NIH Collaboratory Steering Committee Meeting Presentation (2020): Lessons Learned About Embedding Complex Pragmatic Trials in Delivery Systems: Collaborative Care for Chronic Pain

Access the complete set of PPACT resources.

NIH PRAGMATIC TRIALS COLLABORATORY

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PROVEN

PRagmatic Trial of Video Education in Nursing Homes

Pragmatic Trial of Video Education in Nursing Homes (PROVEN)

Principal Investigators
Susan Mitchell, MD, MPH; Angelo Volandes, MD, MPH; Vincent Mor, PhD

ClinicalTrials.gov Identifier
NCT02612688

Sponsoring Institution
Brown University

NIH Institute Providing Oversight
National Institute on Aging (NIA)

DATA AND RESOURCE SHARING

- Data sharing checklist
- **Primary study results:** Mitchell SL, Volandes AE, Gutman R, et al. Advance care planning video intervention among long-stay nursing home residents: a pragmatic cluster randomized clinical trial. *JAMA Intern Med*. 2020;180(8):1070-1078. PMID: 32628258.

STUDY AT A GLANCE

STUDY QUESTION AND SIGNIFICANCE

Nursing homes are often charged with guiding patients through decisions about the direction of their treatment. Identifying effective approaches that nursing homes can use to better promote goal-directed care within existing resources is a research, public health, and clinical priority. Yet, evidenced-based approaches to advance care planning in nursing homes are lacking. The objective of the study was to test the effect of an advance care planning video program on hospital transfers, burdensome treatments, and hospice enrollment among long-stay nursing home residents.

DESIGN AND SETTING

Cluster randomized trial with 197,692 residents in 360 nursing homes in 32 states owned by 2 for-profit corporations, of which 241 facilities were randomly assigned to the control group and 119 facilities were randomly assigned to the intervention.

INTERVENTION AND METHODS

The intervention involved 5 short advance care planning videos made available on tablet computers or online. Designated champions in the intervention facilities were instructed to offer residents or their proxies the opportunity to view a video on admission and every 6 months. Control facilities used usual advance care planning practices. The primary outcome was hospital transfers per 1000 person-days alive among residents with advanced illness. Secondary outcomes included the proportion of residents with or without advanced illness experiencing 1 or more hospital transfer, 1 or more burdensome treatment, and hospice enrollment. The analyses followed the intention-to-treat principle.

FINDINGS

There was no significant reduction in hospital transfers per 1000 person-days alive in the intervention vs control groups. Secondary outcomes did not significantly differ between groups among residents with and without advanced illness. Only 912 of 4171 residents with advanced illness viewed the advance care planning videos. Facility-level rates of showing the videos ranged from 0% to more than 40%.

CONCLUSIONS AND RELEVANCE

The advance care planning video program was not effective in reducing hospital transfers, decreasing burdensome treatment use, or increasing hospice enrollment among long-stay nursing home residents with or without advanced illness. The low level of intervention fidelity highlights the challenges of implementing new programs in nursing homes.

GENERALIZABLE LESSONS

Challenge	Solution
Low implementation fidelity	High level of buy-in from frontline staff responsible for implementing the program, and strong endorsement from healthcare system leadership
Healthcare system interactions	Strong relationships with healthcare systems before the study; study-specific project manager in each healthcare system to oversee the project and serve as liaison between research team and healthcare system

"Becoming integrated into the NIH Collaboratory scientific community was an exceptional experience for all 3 of the PROVEN PIs. Learning from the other investigators and Collaboratory leaders was the definitive highlight. We learned so much, and the experience of PROVEN will lead the way for future pragmatic trials in the nursing home setting." — Susan Mitchell

ADDITIONAL RESOURCES

- Article: Understanding Implementation Fidelity in a Pragmatic Randomized Clinical Trial in the Nursing Home Setting: A Mixed-Methods Examination (2019)
- Article: Proxies Viewing Decision Support Video in Nursing Home Report Higher Advance Care Planning Engagement (2019)
- Article: Black Nursing Home Residents More Likely to Watch Advance Care Planning Video (2020)
- Article: Barriers and Facilitators to Implementing a Pragmatic Trial to Improve Advance Care Planning in the Nursing Home Setting (2019)

Access the complete set of PROVEN resources.

NIH PRAGMATIC TRIALS COLLABORATORY

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